

Measure Information Form

General Characteristics

Measure ID:	<i>(Auto-generated, when entered into QMIS by the Measures Manager)</i>
Measure Name:	ESRD- Vascular Access CPM II: Minimizing use of Catheters as Chronic Dialysis Access
Measure Description:	The percent of patients who are dialyzed with a chronic catheter (90 days or more) prior to the last hemodialysis session during the study period

CMS contact:

Thomas Dudley, MS, RN

Consumer Care Need

- Living With Illness

Quality Domain

- Effectiveness

Type of Measure

- Process

Body System:

Kidney/urinary tract
ESRD

Variable Characteristics

Measure Care Setting

- Ambulance
- Dialysis Facility

Unit of Measurement

- Facility
- Other

National: Stratified by ESRD Network (*QMIS states this*)

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

Continuous Enrollment

- NA

Anchor Date

- Greater than or equal to 18 year old and alive and dialyzing on December 31 of the measurement year

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

Patients who were on maintenance hemodialysis with a chronic catheter continuously for 90 days or longer prior to the last hemodialysis session of the month

Data source

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

Numerator Time Window

One month time period: Data collected for this ESRD CPM are monthly for the in-center hemodialysis patients. However, facilities implementing this measure may choose any time period.

Denominator statement

Patients on maintenance hemodialysis during the last HD treatment of the month.

Data source

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

Denominator Time Window

Monthly

Exclusion Criteria

Patients on acute hemodialysis, peritoneal dialysis, or patients <18 years of age

Data source

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

Exclusion Criteria Time Window

No exclusion time window

History

Measure Status

- Implemented/approved by CMS

CMS Active Implementation Date

- 2/1/09

Measure Developer

- CMS

Intellectual property status

- Public Domain

Measure Source

- Adopted from original measure "Minimizing use of Catheters as Chronic Dialysis Access"

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- Vascular Access CPM II: Minimizing use of catheters as chronic dialysis access
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:

Numerous studies demonstrate that the long-term use of venous catheters as hemodialysis access is associated with increased morbidity and mortality. Whereas it has the advantage of immediate use without need for maturation time, as enumerated in the KDOQI guidelines, the long-term use of catheters is associated with increased morbidity including infectious complications and increased risk for central venous thrombosis, stenosis and occlusion, etc. Finally, as shown by numerous studies, patients receiving dialysis using catheters have been found to have greater mortality risk than patients dialyzed with fistulas, whether or not diabetes mellitus was present.

It is also associated with the highest total costs for patients initiating hemodialysis therapy, with an estimate of \$86,927 as compared to AV fistulas at \$68,220 during the first year of treatment.

Finally, the aggressive policy for reducing catheter use is consistent with the U.S.'s overall goal of improving ESRD outcomes, as demonstrated by the Fistula First Breakthrough Initiative and the goals stated by the ESRD network program.

The following paragraph, which is intended to facilitate the operationalization of the measure, will also be included in the description of the CPM:

Achievement of this measure is possible if all patients are evaluated for a permanent access. A permanent access (preferably AV fistula) should be placed within 30 days of initiating maintenance hemodialysis. All AV fistula not adequately maturing by 30 days or not usable (i.e., in use with two needles) by 60 days should be evaluated for remedial intervention.

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:
Author First Name: Vascular Access Work Group
Title of Chapter or Article: Clinical Practice Guidelines for Vascular Access
Title of Book or Journal: American Journal of Kidney Disease
Publication Date: July 2006
Journal Volume and Number: 48
Pages: S248 - 73
Web link: http://www.kidney.org/Professionals/kdoqi/guideline_upHD_PD_VA/index.htm
Level of Evidence and Rating Scheme:

The percent of patients who are dialyzed with a chronic catheter (90 days or more) prior to the last hemodialysis session during the study period (*Evidence Level B*). Based on National Kidney Foundation Kidney Disease Outcomes Quality Initiative (KDOQI) Guideline: KDOQI Vascular Access Guideline 8.1.2.2 (*Evidence Level B*): Cuffed catheter for permanent dialysis access (eg. not as a bridge) in less than 10% of patients. Long-term catheter access is defined as the use of dialysis catheter for more than 3 months in the absence of a maturing permanent access – graft or fistula. In order to facilitate the achievement of this measure, it is recommended that the following statements be added to the measure (*OPINION*): “Achievement of this measure is possible if all patients are evaluated for a permanent access. A permanent access (preferably AV fistula) should be placed within 30 days of initiating maintenance hemodialysis. All AV fistulas not adequately maturing by 30 days or not usable (i.e. in use with two needles) by 60 days should be evaluated for remedial intervention”.

Reliability of the completion of this CPM is assured by the fact that the clinical community is already familiar with this measure and the data required for the measure is already submitted for the Fistula First Breakthrough Initiative.

The measure’s validity is linked to the increased validity of the prior related measure (CPM I), which specifically defines use of AV fistula.

Literature citation for supporting evidence/study

Author Last Name/Organization:
Author First Name:
Title of Chapter or Article:
Title of Book or Journal:
Publication Date:
Journal Volume and Number:
Pages:
Web link:
Level of Evidence and Rating Scheme:

1. [Allon M, Daugirdas J, Depner TA, Greene T, Ornt D, Schwab SJ](#). Effect of change in vascular access on patient mortality in hemodialysis patients. *Am J Kidney Dis.* 2006 Mar;47(3):469-77. A
2. [Asif A, Merrill D, Leon C, Ellis R, Pennell P](#). Strategies to minimize tunneled hemodialysis catheter use. *Blood Purif.* 2006;24(1):90-4.B
3. [Hemmelgarn BR, Moist L, Pilkey RM, Lok C, Dorval M, Tam PY, Berall MJ, LeBlanc M, Toffelmire EB, Manns BJ, Scott-Douglas N; Canadian Hemodialysis Catheter Working Group](#). Prevention of catheter lumen occlusion with rT-PA versus heparin (Pre-CLOT): study protocol of a randomized trial [ISRCTN35253449]. *BMC Nephrol.* 2006 Apr 11;7:8.C

4. [Unver S, Atasoyu EM, Evrenkaya TR, Ardic N, Ozyurt M.](#) Risk factors for the infections caused by temporary double-lumen hemodialysis catheters. *B Arch Med Res.* 2006 Apr;37(3):348-52.

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>

Please see the attached documents –

[Frankenfield Diane L, Brier Michael E, Bedinger Marjorie R, Milam Roger A, Eggers Paul W, Cain Jeanette A, Aronoff George R., Frederick Pamela R.](#) Evaluation Comparison of Urea Reduction Ratio and Hematocrit Data Reported in Different Data Systems: Results From the Center for Medicare & Medicaid Services and The Renal Network Inc. *American Journal of Kidney Diseases.* 2003 Feb;41(2):433-441

[Rocco Michael V., Frankenfield Diane L., Hopson Sari D., McClellan William M.](#) Relationship between Clinical Performance Measures and Outcomes among Patients Receiving Long-Term Hemodialysis. *Annals of Internal Medicine.* 2006;145:512-519

Adequacy of risk adjustment

Risk Adjustment Not Applicable

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>

The CPM will be applied to “all” patients, without differentiation between prevalent and incident hemodialysis patients. This allows the clear setting of targets that are actionable and that are easy to track. In addition, the inclusion of the descriptive paragraph **“Achievement of this measure is possible if all patients are evaluated for a permanent access. A permanent access (preferably AV fistula) should be placed within 30 days of initiating maintenance hemodialysis. All AV fistula not adequately maturing by 30 days or not usable (i.e., in use with two needles) by 60 days should be evaluated for remedial intervention.”** facilitates the operationalization of this CPM as it sets intermediate targets before the 90 day limit on catheter use is reached.

The statement of the CPM offers a clear and unambiguous message and is a simplification of the prior CPM.

The measure has operational relevance in that it sets clear improvement targets, is under the control of the dialysis provider once the hemodialysis patient is part of the dialysis program, and can be incorporated into a quality improvement program.

Section 4: Feasibility

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

The CPM specifications have been simplified in that it provides a singular target for all chronic hemodialysis patients, removing any differentiation between incident and prevalent patients.

The components of this measure are:

Numerator: number of patients on maintenance hemodialysis using a catheter for ≥ 90 days before the last HD treatment of study period

Denominator: all patients on maintenance hemodialysis at the last HD treatment of study period

Exclusion criteria: patients on acute hemodialysis, peritoneal dialysis, or patients ≤ 18 years of age

These specifications can be used in any sampling frame.

Because the data elements required for the calculation of this measure are already collected as part of the existing ESRD CPM project and the Fistula First Breakthrough Initiative, there will be no increase in burden of data collection.

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. This significantly reduces the data collection burden for this measure.

Comprehensive Reevaluation

<i>Measure ID</i>	(Auto-generated when entered into QMIS)
Measure Set:	Vascular Access
Measure Name (<i>should be brief, concise</i>):	ESRD- Vascular Access CPM II: Minimizing use of Catheters as Chronic Dialysis Access
Measure Description:	The percent of patients who are dialyzed with a chronic catheter (90 days or more) prior to the last hemodialysis session during the study period
CMS GTL/PO:	Thomas Dudley, MS, RN

Version Changes

Summarize what has changed in this version?

There are no revisions to this CPM except to add the recommendation section for this measure. This recommendation stated below facilitates the operationalization of this measure as it provides explicit landmarks so that the measure can be more readily attained.

Recommendation:

Achievement of this measure is possible if all patients are evaluated for a permanent access. A permanent access (preferably AV fistula) should be placed within 30 days of initiating maintenance hemodialysis. All AV fistula not adequately maturing by 30 days or not usable (i.e., in use with two needles) by 60 days should be evaluated for remedial intervention.

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

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

D-TEP: The D-TEP agreed with the wording of CPM II, but in addition, suggested that in order to address the needs of the Fistula First Initiative, more information should be collected on the data collection form regarding vascular access. These suggestions were incorporated in the data collection form.

Public Comments: A public comment raised the issue of the feasibility of the statement “All AV fistula not adequately maturing by 30 days or not usable (i.e., in use with two needles) by 60 days should be evaluated for remedial intervention.” It was clarified that this explanation is NOT part of the measure but is simply a recommendation to help facilitate the operationalization of the actual measure, which is the percent catheter use. As such, the addition of the statements provides a guide to the clinician for early and remedial intervention before the 90-day cut-off for catheter use is met.

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.”

1. [Allon M, Daugirdas J, Depner TA, Greene T, Ornt D, Schwab SJ](#). Effect of change in vascular access on patient mortality in hemodialysis patients. Am J Kidney Dis. 2006 Mar;47(3):469-77. A
2. [Asif A, Merrill D, Leon C, Ellis R, Pennell P](#). Strategies to minimize tunneled hemodialysis catheter use. Blood Purif. 2006;24(1):90-4.B
3. [Hemmelgarn BR, Moist L, Pilkey RM, Lok C, Dorval M, Tam PY, Berall MJ, LeBlanc M, Toffelmire EB, Manns BJ, Scott-Douglas N; Canadian Hemodialysis Catheter Working Group](#). Prevention of catheter lumen occlusion with rT-PA versus heparin (Pre-CLOT): study protocol of a randomized trial [ISRCTN35253449]. BMC Nephrol. 2006 Apr 11;7:8.C
4. [Unver S, Atasoyu EM, Evrenkaya TR, Ardic N, Ozyurt M](#). Risk factors for the infections caused by temporary double-lumen hemodialysis catheters.B Arch Med Res. 2006 Apr;37(3):348-52.

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:

Overview of Recommendations

Summarized below is the current CPM II for vascular access, followed by the TEP's proposed revision(s) to the CPM:

Current CPM II

Minimizing Use of Catheters as Chronic Dialysis Access

Less than 10% of chronic maintenance hemodialysis patients should be maintained on catheters continuously for ≥ 90 days as their permanent chronic dialysis access

Proposed Revised CPM II (no change):

Minimizing Use of Catheters as Chronic Hemodialysis Access

Less than 10% of chronic maintenance hemodialysis patients should be maintained on catheters continuously for ≥ 90 days as their permanent maintenance hemodialysis access.

Numerator:

Number of patients on maintenance hemodialysis using a catheter for ≥ 90 days before the last HD treatment of study period

Denominator:

All patients on maintenance hemodialysis at the last HD treatment of study period

Exclusion criteria:

Patients on acute hemodialysis, peritoneal dialysis, or patients ≤ 18 years of age

Recommendations

Achievement of this measure is possible if all patients are evaluated for a permanent access. A permanent access (preferably AVF) should be placed within 30 days of initiating maintenance hemodialysis. All AVF not adequately maturing by 30 days or not usable (i.e., in use with two needles) by 60 days should be evaluated for remedial intervention.

D-TEP Recommendations:

CPM II: Minimizing the use of catheters as chronic dialysis access.

Current CPM II: Less than 10% of chronic maintenance hemodialysis patients should be maintained on catheters continuously for ≥ 90 days as their permanent chronic dialysis access.

Proposed CPM II Revision (no change): Less than 10% of chronic maintenance hemodialysis patients should be maintained on catheters continuously for ≥ 90 days as their permanent maintenance hemodialysis access.

Comments:

The D-TEP agreed to continue to collect data as is, using Fistula First specifications.

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.

There have been no material changes to this measure.

Measure Contractor Recommended Disposition				
Measure contractor recommended disposition of the measure	<input type="checkbox"/> Retain			
	<input checked="" type="checkbox"/> Revise (as described above)		Effective Date of Action	
			2/09, pending CROWNWeb implementation	
	<input type="checkbox"/> Replace			
	<input type="checkbox"/> Rotate			
	<input type="checkbox"/> Retire			
Rationale for recommendation	No changes were made to this measure. The aggressive policy for reducing catheter use is consistent with the U.S.'s overall goal of improving ESRD outcomes, as demonstrated by the Fistula First Breakthrough Initiative and the goals stated by the ESRD network program.			
Effective date basis	<input type="checkbox"/> Discharges	<input type="checkbox"/> Admissions	<input type="checkbox"/> Service Date	<input type="checkbox"/> Other:
Recommended by	Name: Date:			

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?

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