

NATIONAL QUALITY FORUM

Measure Submission and Evaluation Worksheet 5.0

This form contains the information submitted by measure developers/stewards, organized according to NQF's measure evaluation criteria and process. The evaluation criteria, evaluation guidance documents, and a blank online submission form are available on the [submitting standards web page](#).

NQF #: 0247 NQF Project: Renal Endorsement Maintenance 2011
(for Endorsement Maintenance Review) Original Endorsement Date: Nov 15, 2007 Most Recent Endorsement Date: Nov 15, 2007
BRIEF MEASURE INFORMATION
De.1 Measure Title: Hemodialysis Adequacy Clinical Performance Measure I: Hemodialysis Adequacy- Monthly measurement of delivered dose
Co.1.1 Measure Steward: Centers for Medicare & Medicaid Services
De.2 Brief Description of Measure: Percentage of all adult (>= 18 years old) HD patients in the sample for analyses with documented monthly adequacy measurements (spKt/V) or its components in the calendar month
2a1.1 Numerator Statement: Number of patients in the denominator with documented monthly adequacy measurements (spKt/V) or its components in the calendar month.
2a1.4 Denominator Statement: Number of adult patients (>=18 years) receiving in-center hemodialysis or home hemodialysis (irrespective of frequency of dialysis).
2a1.8 Denominator Exclusions: None.
1.1 Measure Type: Process 2a1. 25-26 Data Source: Electronic Clinical Data 2a1.33 Level of Analysis: Facility
1.2-1.4 Is this measure paired with another measure? No
De.3 If included in a composite, please identify the composite measure (<i>title and NQF number if endorsed</i>):

STAFF NOTES (<i>issues or questions regarding any criteria</i>)
Comments on Conditions for Consideration:
Is the measure untested? Yes <input type="checkbox"/> No <input type="checkbox"/> If untested, explain how it meets criteria for consideration for time-limited endorsement:
1a. Specific national health goal/priority identified by DHHS or NPP addressed by the measure (<i>check De.5</i>): 5. Similar/related endorsed or submitted measures (<i>check 5.1</i>): Other Criteria:
Staff Reviewer Name(s):

1. IMPACT, OPPORTUNITY, EVIDENCE - IMPORTANCE TO MEASURE AND REPORT
Importance to Measure and Report is a threshold criterion that must be met in order to recommend a measure for endorsement. All three subcriteria must be met to pass this criterion. See guidance on evidence . <i>Measures must be judged to be important to measure and report in order to be evaluated against the remaining criteria.</i>

(evaluation criteria)

1a. High Impact: H M L I

(The measure directly addresses a specific national health goal/priority identified by DHHS or NPP, or some other high impact aspect of healthcare.)

De.4 Subject/Topic Areas *(Check all the areas that apply):* Renal : End Stage Renal Disease (ESRD)

De.5 Cross Cutting Areas *(Check all the areas that apply):* Population Health

1a.1 Demonstrated High Impact Aspect of Healthcare: Frequently performed procedure, High resource use, Patient/societal consequences of poor quality

1a.2 If "Other," please describe:

1a.3 Summary of Evidence of High Impact *(Provide epidemiologic or resource use data):*

At the end of 2008 there were 354,600 patients treated with HD in the United States (US), which accounts for 93% of all dialysis patients. During that year 112,476 patients started end-stage renal Disease (ESRD) therapy with HD [1].

The dose of dialysis is used to estimate the ability of hemodialysis to clear the blood of accumulated toxins. In the adult ESRD population, outcome studies, many of which uses a monthly interval of measurement of hemodialysis dose, have shown an association between dose of hemodialysis in terms of small solute removal and clinical outcomes including mortality and morbidity [2-6]. In addition, at least one prior study demonstrates that a change in dialysis dose is associated with a change in patient outcome [7]. In order to ensure that patients receive adequate dose of dialysis, regular monitoring of dialysis dose would need to be performed. Studies of delivered dialysis dose and clinical outcomes use monthly measurements of dialysis dose. As such, for this measure maintenance cycle, we propose that this measure remains in its current format with the potential for Technical Expert Panel review as necessary.

1a.4 Citations for Evidence of High Impact cited in 1a.3: 1. USRDS 2010 ADR,

<http://www.usrds.org/2010/slides/indiv/1v2index.html>

2. Eknoyan G, Beck GJ, Cheung AK, et al: Effect of dialysis dose and membrane flux in maintenance hemodialysis. N Engl J Med 347:2010-2019, 2002.

3. Depner T, Daugirdas J, Greene T, et al: Dialysis dose and the effect of gender and body size on outcome in the HEMO Study. Kidney Int 65:1386-1394, 2004.

4. Termorshuizen F, Dekker FW, van Manen JG, Korevaar JC, Boeschoten EW, Krediet RT: Relative contribution of residual renal function and different measures of adequacy to survival in hemodialysis patients: An analysis of the Netherlands Cooperative Study on the Adequacy of Dialysis (NECOSAD)-2. J Am Soc Nephrol 15:1061-1070, 2004.

5. Port FK, Wolfe RA, Hulbert-Shearon TE, McCullough KP, Ashby VB, Held PJ: High dialysis dose is associated with lower mortality among women but not among men. Am J Kidney Dis 43:1014-1023, 2004.

6. Port FK, Ashby VB, Dhingra RK, Roys EC, Wolfe RA: Dialysis dose and body mass index are strongly associated with survival in hemodialysis patients. J Am Soc Nephrol 13:1061-1066, 2002.

7. Wolfe RA, Hulbert-Shearon TE, Ashby VB, Mahavadevan S, Port FK: Improvements in dialysis patient mortality are associated with Urea Reduction Ratio and Hematocrit, 1999 to 2002. Am J Kidney Dis 45(1):127-135, 2005.

1b. Opportunity for Improvement: H M L I

(There is a demonstrated performance gap - variability or overall less than optimal performance)

1b.1 Briefly explain the benefits (improvements in quality) envisioned by use of this measure:

A minimum of monthly evaluation of HD adequacy is critical to ensure timely dose adjustment as needed. Less frequent measurements may compromise the timeliness with which deficiencies in the delivered dose of HD are detected and hence may delay implementation of corrective action. Therefore, continued implementation of this measure is needed to ensure frequent adequacy measurement.

1b.2 Summary of Data Demonstrating Performance Gap *(Variation or overall less than optimal performance across providers):*

[For Maintenance – Descriptive statistics for performance results for this measure - distribution of scores for measured entities by quartile/decile, mean, median, SD, min, max, etc.]

Analysis of CROWNWeb data from January 2010 indicated the facility-level mean percentage of patients with monthly HD adequacy measurements was 75% (SD=21%). Distribution: Min=0%, Max=100%, 1st quartile=67%, median=79%, 3rd

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quartile=88%.

These results indicate that on average, facilities are not measuring hemodialysis adequacy monthly in 25% of HD patients. Furthermore, only 18% of facilities had at least 90% of patients meeting the requirements for this measure.

1b.3 Citations for Data on Performance Gap: [*For Maintenance* – Description of the data or sample for measure results reported in 1b.2 including number of measured entities; number of patients; dates of data; if a sample, characteristics of the entities included] Performance gap analyses were performed using CROWNWeb data from January 2010. There were 3436 facilities and a total of 293,694 patients in this reporting month. Mean number of patients per facility was 84 (SD=52).

1b.4 Summary of Data on Disparities by Population Group: [*For Maintenance* –Descriptive statistics for performance results for this measure by population group]

For each facility, the percent of patients by demographic group including sex, race, ethnicity, and age category, was calculated. Facilities were then divided into quintiles based on their percentage within each demographic category. Within each facility-level quintile, the average of each facility's performance measure was calculated. The means were examined for trend across quintile. No disparities in performance were observed by race, sex, ethnicity, or age. The range in percent of patients with monthly HD adequacy measurements across quintiles is presented below.

- Population Group (Range):
- Females (78.0%-79.4%)
- Males (78.0%-79.4%)
- Black (77.6%-79.8%)
- White (77.1%-79.7%)
- Hispanic (78.0%-79.1%)
- Age Category (78.1%-80.1%)

1b.5 Citations for Data on Disparities Cited in 1b.4: [*For Maintenance* – Description of the data or sample for measure results reported in 1b.4 including number of measured entities; number of patients; dates of data; if a sample, characteristics of the entities included] CROWNWeb data from July 2009-October 2010 were analyzed. The number of facilities ranged from 3398-3453 and the total number of patients per month ranged from 263,743 - 290,713.

1c. Evidence (*Measure focus is a health outcome OR meets the criteria for quantity, quality, consistency of the body of evidence.*)
Is the measure focus a health outcome? Yes No **If not a health outcome**, rate the body of evidence.

Quantity: H M L I Quality: H M L I Consistency: H M L I

Quantity	Quality	Consistency	Does the measure pass subcriterion1c?
M-H	M-H	M-H	Yes <input type="checkbox"/>
L	M-H	M	Yes <input type="checkbox"/> IF additional research unlikely to change conclusion that benefits to patients outweigh harms: otherwise No <input type="checkbox"/>
M-H	L	M-H	Yes <input type="checkbox"/> IF potential benefits to patients clearly outweigh potential harms: otherwise No <input type="checkbox"/>
L-M-H	L-M-H	L	No <input type="checkbox"/>

Health outcome – rationale supports relationship to at least one healthcare structure, process, intervention, or service	Does the measure pass subcriterion1c? Yes <input type="checkbox"/> IF rationale supports relationship
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1c.1 Structure-Process-Outcome Relationship (*Briefly state the measure focus, e.g., health outcome, intermediate clinical outcome, process, structure; then identify the appropriate links, e.g., structure-process-health outcome; process- health outcome; intermediate clinical outcome-health outcome*):

The measure focus is the process of measuring hemodialysis adequacy every month for ESRD dialysis patients.

This process leads to improvement in mortality as follows:

Measure spKt/V--> Assess value-->Identify problem-->Identify treatment options-->Administer the appropriate treatment-->Impact on mortality.

1c.2-3 Type of Evidence (Check all that apply):

Clinical Practice Guideline, Selected individual studies (rather than entire body of evidence)

1c.4 Directness of Evidence to the Specified Measure (State the central topic, population, and outcomes addressed in the body of evidence and identify any differences from the measure focus and measure target population):

The body of evidence shows a relationship between low spKt/V and improved mortality and morbidity. This measure focus is on the frequency of measuring hemodialysis adequacy, or spKt/V, in ESRD patients on HD. Studies that evaluate the relationship between dialysis dose and patient outcomes used monthly measurement of dialysis adequacy in their analyses.

1c.5 Quantity of Studies in the Body of Evidence (Total number of studies, not articles): 11

1c.6 Quality of Body of Evidence (Summarize the certainty or confidence in the estimates of benefits and harms to patients across studies in the body of evidence resulting from study factors. Please address: a) study design/flaws; b) directness/indirectness of the evidence to this measure (e.g., interventions, comparisons, outcomes assessed, population included in the evidence); and c) imprecision/wide confidence intervals due to few patients or events): The body of evidence show a correlation between delivered dose of HD and patient mortality and morbidity. Monthly measurement was used to assess the impact of delivered dose. Thus, this evidence indirectly supports the measure as delivered dose of dialysis should be measured regularly for assessment of adequate treatment. Of the 11 studies, 9 measured delivered dose at least monthly [1-5,7,9,10]. Two studies were based on the HEMO study, which was a randomized clinical trial (HEMO study) with 1846 patients [1,2], two were prospective studies with 740 and 10,000 patients [3,4], and the remaining were retrospective cohort studies with sample sizes ranging from 1,151 to 74,000 patients.

Three of the eight studies measured URR [4,5,7]. One study found a significant association between increased URR and lower mortality among all patients; one also found higher URR was associated with lower mortality, but only among women; and one study found no significant association between URR and mortality.

Three studies measured dialysis adequacy monthly using spKt/v [1,3,9]. One study found a significant improvement in mortality with increasing dose of spKt/V [3]. One study compared high doses of spKt/V to the standard dose (>2.4 vs. 1.2-1.3) and found a significantly higher mortality rate among those receiving high doses [9]. The HEMO study compared a high dose group to the low dose group (1.53 vs. 1.16) and found the higher doses did not improve mortality compared to the low dose[1]. However, in a prespecified subgroup analysis, women randomized to the "conventional" (lower) dose had a higher mortality than women randomized to the higher dose.

1c.7 Consistency of Results across Studies (Summarize the consistency of the magnitude and direction of the effect): Results were consistent across studies. Six of the nine studies measuring adequacy at least monthly found higher dialysis dose was associated with lower mortality [2-5,9] Two of these studies only found this association among women [2,4]. Two studies compared higher doses of spKt/V to the standard dose and found that increasing dose above the standard dose did not improve mortality [1,9]. The remaining study assessed URR categories and did not find improved survival among patients with doses lower or higher than the standard URR percentage [7].

1c.8 Net Benefit (Provide estimates of effect for benefit/outcome; identify harms addressed and estimates of effect; and net benefit - benefit over harms):

Among the studies showing a significant improvement in mortality in high dialysis dose vs. low dialysis dose, relative risks ranged from 0.76-0.86 [3-5]. These studies all show a benefit of higher dose of dialysis. Studies showing no association between dialysis dose and mortality focused on higher doses and compared to patients receiving the standard dose [1,9].

1c.9 Grading of Strength/Quality of the Body of Evidence. Has the body of evidence been graded? Yes

1c.10 If body of evidence graded, identify the entity that graded the evidence including balance of representation and any disclosures regarding bias: The body of evidence was rated in the KDOQI Guidelines. Two of the studies were graded A, one received a B, and the remaining were graded C.

1c.11 System Used for Grading the Body of Evidence: GRADE

1c.12 If other, identify and describe the grading scale with definitions:

1c.13 Grade Assigned to the Body of Evidence: An overall grade was not assigned.

1c.14 Summary of Controversy/Contradictory Evidence: No controversial or contradictory evidence was found.

1c.15 Citations for Evidence other than Guidelines (*Guidelines addressed below*):

1. Eknoyan G, Beck GJ, Cheung AK, et al: Effect of dialysis dose and membrane flux in maintenance hemodialysis. N Engl J Med 347:2010-2019, 2002.
2. Termorshuizen F, Dekker FW, van Manen JG, Korevaar JC, Boeschoten EW, Krediet RT: Relative contribution of residual renal function and different measures of adequacy to survival in hemodialysis patients: An analysis of the Netherlands Cooperative Study on the Adequacy of Dialysis (NECOSAD)-2. J Am Soc Nephrol 15:1061-1070, 2004.
3. Port FK, Wolfe RA, Hulbert-Shearon TE, McCullough KP, Ashby VB, Held PJ: High dialysis dose is associated with lower mortality among women but not among men. Am J Kidney Dis 43:1014-1023, 2004.
4. Port FK, Ashby VB, Dhingra RK, Roys EC, Wolfe RA: Dialysis dose and body mass index are strongly associated with survival in hemodialysis patients. J Am Soc Nephrol 13:1061-1066, 2002.
5. Chertow GM, Owen WF, Lazarus JM, Lew NL, Lowrie EG: Exploring the reverse J-shaped curve between urea reduction ratio and mortality. Kidney Int 56:1872-1878, 1999
6. Salahudeen AK, Dykes P, May W: Risk factors for higher mortality at the highest levels of spKt/V in hemodialysis patients. Nephrol Dial Transplant 18:1339-1344, 2003
7. Wolfe RA, Ashby VB, Daugirdas JT, Agodoa LY, Jones CA, Port FK: Body size, dose of hemodialysis, and mortality. Am J Kidney Dis 35:80-88, 2000

1c.16 Quote verbatim, the specific guideline recommendation (Including guideline # and/or page #):

- I. Clinical Practice Guidelines for Hemodialysis Adequacy
- GUIDELINE 2. Methods for Measuring and Expressing the Hemodialysis dose
- 2.1 The delivered dose of HD should be measured at regular intervals no less than monthly. (A)

1c.17 Clinical Practice Guideline Citation: National Kidney Foundation. KDOQI Clinical Practice Guidelines and Clinical Practice Recommendations for Hemodialysis Adequacy, Update 2006.

1c.18 National Guideline Clearinghouse or other URL:

http://www.kidney.org/professionals/KDOQI/guideline_upHD_PD_VA/index.htm

1c.19 Grading of Strength of Guideline Recommendation. Has the recommendation been graded? Yes

1c.20 If guideline recommendation graded, identify the entity that graded the evidence including balance of representation and any disclosures regarding bias: KDOQI members graded this guideline.

1c.21 System Used for Grading the Strength of Guideline Recommendation: GRADE

1c.22 If other, identify and describe the grading scale with definitions:

1c.23 Grade Assigned to the Recommendation: A

1c.24 Rationale for Using this Guideline Over Others: No other guidelines are available.

Based on the NQF descriptions for rating the evidence, what was the developer's assessment of the quantity, quality, and consistency of the body of evidence?

1c.25 Quantity: High 1c.26 Quality: High 1c.27 Consistency: High

Was the threshold criterion, *Importance to Measure and Report*, met?
(1a & 1b must be rated moderate or high and 1c yes) Yes No

Provide rationale based on specific subcriteria:

For a new measure if the Committee votes NO, then STOP.
For a measure undergoing endorsement maintenance, if the Committee votes NO because of 1b. (no opportunity for improvement), it may be considered for continued endorsement and all criteria need to be evaluated.

2. RELIABILITY & VALIDITY - SCIENTIFIC ACCEPTABILITY OF MEASURE PROPERTIES

Extent to which the measure, as specified, produces consistent (reliable) and credible (valid) results about the quality of care when implemented. **(evaluation criteria)**

Measure testing must demonstrate adequate reliability and validity in order to be recommended for endorsement. Testing may be conducted for data elements and/or the computed measure score. Testing information and results should be entered in the appropriate field. Supplemental materials may be referenced or attached in item 2.1. See [guidance on measure testing](#).

S.1 Measure Web Page (*In the future, NQF will require measure stewards to provide a URL link to a web page where current detailed specifications can be obtained*). Do you have a web page where current detailed specifications for this measure can be obtained? [Yes](#)

S.2 If yes, provide web page URL: http://www.arborresearch.org/ESRD_QMS.aspx

2a. RELIABILITY. Precise Specifications and Reliability Testing: H M L I

2a1. Precise Measure Specifications. (*The measure specifications precise and unambiguous.*)

2a1.1 Numerator Statement (*Brief, narrative description of the measure focus or what is being measured about the target population, e.g., cases from the target population with the target process, condition, event, or outcome*):

Number of patients in the denominator with documented monthly adequacy measurements (spKt/V) or its components in the calendar month.

2a1.2 Numerator Time Window (*The time period in which the target process, condition, event, or outcome is eligible for inclusion*):
[The entire calendar month.](#)

2a1.3 Numerator Details (*All information required to identify and calculate the cases from the target population with the target process, condition, event, or outcome such as definitions, codes with descriptors, and/or specific data collection items/responses*):

The numerator will be determined by counting the patients in the denominator who meet one of the following criteria in the one month study period: "Kt/V Hemodialysis Collection Date" is populated, AND "Kt/V Hemodialysis" is populated, OR "Kt/V Hemodialysis Collection Date" is populated, AND "BUN Pre-Dialysis" is populated, AND "BUN Post-Dialysis" is populated, AND "Pre-Dialysis Weight" is populated, AND "Pre-Dialysis Weight Unit of Measure" is populated, AND "Post-Dialysis Weight" is populated, AND "Post-Dialysis Weight Unit of Measure" is populated, AND "Delivered Minutes of BUN Hemodialysis Session" is populated.

2a1.4 Denominator Statement (*Brief, narrative description of the target population being measured*):

Number of adult patients (>=18 years) receiving in-center hemodialysis or home hemodialysis (irrespective of frequency of dialysis).

2a1.5 Target Population Category (*Check all the populations for which the measure is specified and tested if any*): [Adult/Elderly Care](#)

2a1.6 Denominator Time Window (*The time period in which cases are eligible for inclusion*):

[The entire calendar month.](#)

2a1.7 Denominator Details (*All information required to identify and calculate the target population/denominator such as definitions, codes with descriptors, and/or specific data collection items/responses*):

The patient's age will be determined by subtracting the patient's date of birth from the first day of the reporting month. Hemodialysis patients are defined as follows: "Admit Date" to the specified facility is prior or equal to the first day of the study period, AND the patient has not been discharged ("Discharge Date" is null or blank), OR "Discharge Date" from the facility is greater than or equal to the last day of the study period AND "Treatment Dialysis Broad Start Date" is prior or equal to the first day of the study period, AND "Dialysis Broad Type of Treatment" = 'HD', AND "Primary Dialysis Setting" = 'Dialysis Facility/Center' or 'Home' on the last day of

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the study period, AND "Date Regular Chronic Dialysis Began" is prior to the first day of the study period. The denominator will include all patients greater than or equal to 18 years old who are determined to be in-center hemodialysis or home hemodialysis patients.

2a1.8 Denominator Exclusions (Brief narrative description of exclusions from the target population):
None.

2a1.9 Denominator Exclusion Details (All information required to identify and calculate exclusions from the denominator such as definitions, codes with descriptors, and/or specific data collection items/responses):
None.

2a1.10 Stratification Details/Variables (All information required to stratify the measure results including the stratification variables, codes with descriptors, definitions, and/or specific data collection items/responses):
No stratification is required for this measure.

2a1.11 Risk Adjustment Type (Select type. Provide specifications for risk stratification in 2a1.10 and for statistical model in 2a1.13): No risk adjustment or risk stratification **2a1.12 If "Other," please describe:**

2a1.13 Statistical Risk Model and Variables (Name the statistical method - e.g., logistic regression and list all the risk factor variables. Note - risk model development should be addressed in 2b4.):
No risk adjustment necessary.

2a1.14-16 Detailed Risk Model Available at Web page URL (or attachment). Include coefficients, equations, codes with descriptors, definitions, and/or specific data collection items/responses. Attach documents only if they are not available on a webpage and keep attached file to 5 MB or less. NQF strongly prefers you make documents available at a Web page URL. Please supply login/password if needed:

2a1.17-18. Type of Score: Rate/proportion

2a1.19 Interpretation of Score (Classifies interpretation of score according to whether better quality is associated with a higher score, a lower score, a score falling within a defined interval, or a passing score): Better quality = Higher score

2a1.20 Calculation Algorithm/Measure Logic (Describe the calculation of the measure score as an ordered sequence of steps including identifying the target population; exclusions; cases meeting the target process, condition, event, or outcome; aggregating data; risk adjustment; etc.):

For this measure calculation, the numerator will be divided by the denominator.

Calculation of the numerator and denominator is described below.

The patient's age will be determined by subtracting the patient's date of birth from the first day of the reporting month. Hemodialysis patients are defined as follows: "Admit Date" to the specified facility is prior or equal to the first day of the study period, AND the patient has not been discharged ("Discharge Date" is null or blank), OR "Discharge Date" from the facility is greater than or equal to the last day of the study period AND "Treatment Dialysis Broad Start Date" is prior or equal to the first day of the study period, AND "Dialysis Broad Type of Treatment" = 'HD', AND "Primary Dialysis Setting" = 'Dialysis Facility/Center' on the last day of the study period, AND "Date Regular Chronic Dialysis Began" is prior to the first day of the study period. Home hemodialysis patients are determined by "Primary Dialysis Setting" = "Home" on the last day of the study period. The denominator will include all patients greater than or equal to 18 years old who are determined to be in-center hemodialysis or home hemodialysis patients.

The numerator will be determined by counting the patients in the denominator who meet one of the following criteria in the one month study period: "Kt/V Hemodialysis Collection Date" is populated, AND "Kt/V Hemodialysis" is populated, OR "Kt/V Hemodialysis Collection Date" is populated, AND "BUN Pre-Dialysis" is populated, AND "BUN Post-Dialysis" is populated, AND "Pre-Dialysis Weight" is populated, AND "Pre-Dialysis Weight Unit of Measure" is populated, AND "Post-Dialysis Weight" is populated, AND "Post-Dialysis Weight Unit of Measure" is populated, AND "Delivered Minutes of BUN Hemodialysis Session" is

populated.

2a1.21-23 Calculation Algorithm/Measure Logic Diagram URL or attachment:

Attachment

[Appendix C CPM Calculation Flow charts_a 3-634444292958527360.pdf](#)

2a1.24 **Sampling (Survey) Methodology.** If measure is based on a sample (or survey), provide instructions for obtaining the sample, conducting the survey and guidance on minimum sample size (response rate):

N/A

2a1.25 **Data Source** (*Check all the sources for which the measure is specified and tested*). If other, please describe:

[Electronic Clinical Data](#)

2a1.26 **Data Source/Data Collection Instrument** (*Identify the specific data source/data collection instrument, e.g. name of database, clinical registry, collection instrument, etc.*): [CROWNWeb](#)

2a1.27-29 **Data Source/data Collection Instrument Reference Web Page URL or Attachment:** URL

<http://www.projectcrownweb.org>

2a1.30-32 **Data Dictionary/Code Table Web Page URL or Attachment:**

URL

http://projectcrownweb.org/crown/index.php?page=Public_Documents&subPage=Release_Documents

2a1.33 **Level of Analysis** (*Check the levels of analysis for which the measure is specified and tested*): [Facility](#)

2a1.34-35 **Care Setting** (*Check all the settings for which the measure is specified and tested*): [Dialysis Facility](#)

2a2. **Reliability Testing.** (*Reliability testing was conducted with appropriate method, scope, and adequate demonstration of reliability.*)

2a2.1 **Data/Sample** (*Description of the data or sample including number of measured entities; number of patients; dates of data; if a sample, characteristics of the entities included*):

CROWNWeb is currently being released in phases, to allow the immediate collection of data from a limited number of facilities while providing future users an opportunity to complete the required steps to access the system. CMS moved into Phase II of its phase-in implementation process in July 2009. Data were collected from Phase II facilities and test batch submitters on a voluntary basis. These data are not a random national sample of facilities and hence results are not necessarily representative.

CROWNWeb data from July 2009-October 2010 were analyzed. The number of facilities ranged from 3415-3453. The total number of patients per month ranged from 263,743 - 290,713.

2a2.2 **Analytic Method** (*Describe method of reliability testing & rationale*):

Reliability was assessed by calculating facility-level month-to-month correlations. Pearson correlation coefficients were calculated between the current performance month and previous month for reporting months July 2009 through October 2010.

2a2.3 **Testing Results** (*Reliability statistics, assessment of adequacy in the context of norms for the test conducted*):

Reliability of this measure has improved over time. Correlation coefficients ranged from 0.66 to 0.95. The lowest correlation was observed in the first two reporting months. In 2010, correlations from month-to-month were high (range: 0.74-0.95), thus indicating the data elements for this measure are reliable.

2b. **VALIDITY. Validity, Testing, including all Threats to Validity:** H M L I

2b1.1 Describe how the measure specifications (*measure focus, target population, and exclusions*) are consistent with the evidence cited in support of the measure focus (*criterion 1c*) and identify any differences from the evidence:

The target population in the validity analysis was all ESRD patients on HD who are reported in CROWNWeb in 2009. The population and results from the validity analyses performed were consistent with the evidence provided. The validity analyses showed that relative to facilities with the highest performance scores, the Standardized Mortality Ratio (SMR) increased as performance scores decreased.

2b2. Validity Testing. (*Validity testing was conducted with appropriate method, scope, and adequate demonstration of validity.*)

2b2.1 Data/Sample (*Description of the data or sample including number of measured entities; number of patients; dates of data; if a sample, characteristics of the entities included*):

2009 CROWNWeb data (July - December) were used to calculate monthly performance scores, and the SMR was calculated using 2009 Medicare-paid dialysis claims and the Medical Evidence Form (Form CMS-2728). Documentation regarding the Medicare claims used to calculate the SMR is attached.

2b2.2 Analytic Method (*Describe method of validity testing and rationale; if face validity, describe systematic assessment*):

Validity was assessed using Poisson regression models to measure the association between facility level quintiles of performance scores and the 2009 SMR (methodology on SMR calculations is attached). Facility-level performance scores were divided into quintiles and the relative risk (RR) of mortality was calculated for each quintile. The highest quintile was used as the reference group. Thus, a RR>1.0 for the lower performance score quintiles would indicate a higher relative risk of mortality.

2b2.3 Testing Results (*Statistical results, assessment of adequacy in the context of norms for the test conducted; if face validity, describe results of systematic assessment*):

Quintiles of the performance scores were defined as follows:

Q1:0-<70%

Q2:70%-<78%

Q3:78%-<85%

Q4:85%-<90%

Q5:90%-100%

Results from the Poisson model indicated lower performance scores were significantly associated with increased mortality as calculated by SMR ($p<0.0001$). Relative risks of mortality was highest in the lowest performance measure quintile (RR=1.13;95% CI: 1.09,1.17). For quintiles 2 and 3, RR=1.08 (95% CI:1.05,1.13), and for quintile 4, RR=1.09 (95% CI:1.04,1.12).

These findings demonstrate the association between frequent (monthly) evaluation of hemodialysis adequacy and improved mortality.

POTENTIAL THREATS TO VALIDITY. (*All potential threats to validity were appropriately tested with adequate results.*)

2b3. Measure Exclusions. (*Exclusions were supported by the clinical evidence in 1c or appropriately tested with results demonstrating the need to specify them.*)

2b3.1 Data/Sample for analysis of exclusions (*Description of the data or sample including number of measured entities; number of patients; dates of data; if a sample, characteristics of the entities included*):

CROWNWeb data from July through December 2009 included up to 3495 facilities per month with an average of 80 patients per facility. The total number of patients per month ranged from 267,515 - 290,713. There are no exclusions for this measure.

2b3.2 Analytic Method (*Describe type of analysis and rationale for examining exclusions, including exclusion related to patient preference*):

Not applicable; there are no exclusions for this measure.

2b3.3 Results (*Provide statistical results for analysis of exclusions, e.g., frequency, variability, sensitivity analyses*):

Not applicable.

2b4. Risk Adjustment Strategy. (*For outcome measures, adjustment for differences in case mix (severity) across measured entities was appropriately tested with adequate results.*)

2b4.1 Data/Sample (*Description of the data or sample including number of measured entities; number of patients; dates of data; if a sample, characteristics of the entities included*):

No risk adjustment is performed for this measure.

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2b4.2 Analytic Method (*Describe methods and rationale for development and testing of risk model or risk stratification including selection of factors/variables*):

Not applicable

2b4.3 Testing Results (*Statistical risk model: Provide quantitative assessment of relative contribution of model risk factors; risk model performance metrics including cross-validation discrimination and calibration statistics, calibration curve and risk decile plot, and assessment of adequacy in the context of norms for risk models. Risk stratification: Provide quantitative assessment of relationship of risk factors to the outcome and differences in outcomes among the strata*):

Not applicable

2b4.4 If outcome or resource use measure is not risk adjusted, provide rationale and analyses to justify lack of adjustment: Disparities by population group were not observed (see results in Section 1b.4). Adequate dialysis dose is beneficial in all population groups. Furthermore, there is no evidence suggesting this measure should be risk adjusted.

2b5. Identification of Meaningful Differences in Performance. (*The performance measure scores were appropriately analyzed and discriminated meaningful differences in quality.*)

2b5.1 Data/Sample (*Describe the data or sample including number of measured entities; number of patients; dates of data; if a sample, characteristics of the entities included*):

Analyses were performed using CROWNWeb data from January 2010. There were 3436 facilities and a total of 293,694 patients in this reporting month. Mean number of patients per facility was 84 (SD=52).

2b5.2 Analytic Method (*Describe methods and rationale to identify statistically significant and practically/meaningfully differences in performance*):

Facility-level percents of patients with monthly HD adequacy measures were calculated as the number of patients within the facility with spKt/V reported divided by the total number of patients in the facility. The mean, SD, and quartiles also were calculated.

2b5.3 Results (*Provide measure performance results/scores, e.g., distribution by quartile, mean, median, SD, etc.; identification of statistically significant and meaningful differences in performance*):

Analysis of CROWNWeb data from January 2010 showed the mean percentage of patients with monthly HD adequacy measurements was 75% (SD=21%). Distribution: Min=0%, Max=100%, 1st quartile=67%, median=79%, 3rd quartile=88%. Additionally, assessment of the facility-level distribution of the percent of patients with monthly HD measurements indicates that 86% (N=2994) of facilities are measuring HD monthly in at least 60% of patients. Additionally, nearly 5% (N=165) of facilities are only measuring HD on a monthly basis in 10% or fewer patients.

2b6. Comparability of Multiple Data Sources/Methods. (*If specified for more than one data source, the various approaches result in comparable scores.*)

2b6.1 Data/Sample (*Describe the data or sample including number of measured entities; number of patients; dates of data; if a sample, characteristics of the entities included*):

Multiple data sources were not used.

2b6.2 Analytic Method (*Describe methods and rationale for testing comparability of scores produced by the different data sources specified in the measure*):

Not applicable.

2b6.3 Testing Results (*Provide statistical results, e.g., correlation statistics, comparison of rankings; assessment of adequacy in the context of norms for the test conducted*):

Not applicable.

2c. Disparities in Care: H M L I NA (*If applicable, the measure specifications allow identification of disparities.*)

2c.1 If measure is stratified for disparities, provide stratified results (*Scores by stratified categories/cohorts*): This measure is not stratified.

2c.2 If disparities have been reported/identified (e.g., in 1b), but measure is not specified to detect disparities, please explain:

No disparities have been identified.

2.1-2.3 Supplemental Testing Methodology Information:

Attachment
SMRdocumentation.pdf

Steering Committee: Overall, was the criterion, *Scientific Acceptability of Measure Properties*, met?

(Reliability and Validity must be rated moderate or high) Yes No

Provide rationale based on specific subcriteria:

If the Committee votes No, STOP

3. USABILITY

Extent to which intended audiences (e.g., consumers, purchasers, providers, policy makers) can understand the results of the measure and are likely to find them useful for decision making. (evaluation criteria)

C.1 Intended Purpose/ Use (Check all the purposes and/or uses for which the measure is intended): Public Reporting, Quality Improvement (Internal to the specific organization), Quality Improvement with Benchmarking (external benchmarking to multiple organizations)

3.1 Current Use (Check all that apply; for any that are checked, provide the specific program information in the following questions): Public Reporting, Quality Improvement (Internal to the specific organization)

3a. Usefulness for Public Reporting: H M L I

(The measure is meaningful, understandable and useful for public reporting.)

3a.1. Use in Public Reporting - disclosure of performance results to the public at large (If used in a public reporting program, provide name of program(s), locations, Web page URL(s)). If not publicly reported in a national or community program, state the reason AND plans to achieve public reporting, potential reporting programs or commitments, and timeline, e.g., within 3 years of endorsement: [For Maintenance - If not publicly reported, describe progress made toward achieving disclosure of performance results to the public at large and expected date for public reporting; provide rationale why continued endorsement should be considered.]

Quality measure results will then be evaluated for public reporting, potentially on Medicare's Dialysis Facility Compare website.

3a.2. Provide a rationale for why the measure performance results are meaningful, understandable, and useful for public reporting. If usefulness was demonstrated (e.g., focus group, cognitive testing), describe the data, method, and results: Healthcare providers and patients can easily understand the meaning of this measure. The measure is well-accepted by the Nephrology community and is supported by clinical practice guidelines. The percent of patients with monthly adequacy measurements improved from 79% in 1998 to 87% in 2007.

3.2 Use for other Accountability Functions (payment, certification, accreditation). If used in a public accountability program, provide name of program(s), locations, Web page URL(s): The use of spKt/V to measure dialysis adequacy is currently in use for a CMS Quality Incentive Payment Demonstration Evaluation, a related project of the CMS Disease Management Demonstration Evaluation.

[http://www.nephronline.com/assets/documents/SpecialSectionsReports/QIP%20Report_final\(2\).pdf](http://www.nephronline.com/assets/documents/SpecialSectionsReports/QIP%20Report_final(2).pdf)

3b. Usefulness for Quality Improvement: H M L I

(The measure is meaningful, understandable and useful for quality improvement.)

3b.1. Use in QI. If used in quality improvement program, provide name of program(s), locations, Web page URL(s):

[For Maintenance - If not used for QI, indicate the reasons and describe progress toward using performance results for improvement].

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The use of spKt/V to measure dialysis adequacy has been used in multiple quality improvement programs. An example is an initiative of ESRD Network 5 to improve performance for achieving spKt/V targets (<http://www.esrdnet5.org/adequacyproj.asp>). Similarly ESRD Network 18 includes spKt/V for its quality improvement initiatives (<http://www.esrdnetwork18.org/pdfs/QI%20-%20Tools%20&%20Forms/2010-2011%20Clinical%20Performance%20Goals-FINAL.pdf>). Also, in previous years, this measure was reported in ESRD CPM Annual Reports. The ESRD CPM Project was a national effort designed to assist dialysis providers to improve patient care and outcomes.

3b.2. Provide rationale for why the measure performance results are meaningful, understandable, and useful for quality improvement. If usefulness was demonstrated (e.g., *QI initiative*), describe the data, method and results:
See response in 3a.2.

Overall, to what extent was the criterion, *Usability*, met? H M L I
Provide rationale based on specific subcriteria:

4. FEASIBILITY

Extent to which the required data are readily available, retrievable without undue burden, and can be implemented for performance measurement. (evaluation criteria)

4a. Data Generated as a Byproduct of Care Processes: H M L I

4a.1-2 How are the data elements needed to compute measure scores generated? (*Check all that apply*).

Data used in the measure are:

Abstracted from a record by someone other than person obtaining original information (e.g., chart abstraction for quality measure or registry)

4b. Electronic Sources: H M L I

4b.1 Are the data elements needed for the measure as specified available electronically (*Elements that are needed to compute measure scores are in defined, computer-readable fields*): ALL data elements in electronic health records (EHRs)

4b.2 If ALL data elements are not from electronic sources, specify a credible, near-term path to electronic capture, OR provide a rationale for using other than electronic sources:

4c. Susceptibility to Inaccuracies, Errors, or Unintended Consequences: H M L I

4c.1 Identify susceptibility to inaccuracies, errors, or unintended consequences of the measurement identified during testing and/or operational use and strategies to prevent, minimize, or detect. If audited, provide results:

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

4d. Data Collection Strategy/Implementation: H M L I

A.2 Please check if either of the following apply (*regarding proprietary measures*):

4d.1 Describe what you have learned/modified as a result of testing and/or operational use of the measure regarding data collection, availability of data, missing data, timing and frequency of data collection, sampling, patient confidentiality, time and cost of data collection, other feasibility/implementation issues (e.g., *fees for use of proprietary measures*):

Since this measure has been collected for several years as part of the CPM project, facilities are familiar with the data required for this measure, and data are readily available. It is unlikely that data elements will be susceptible to inaccuracies, errors, or unintended consequences.

Overall, to what extent was the criterion, *Feasibility*, met? H M L I

Provide rationale based on specific subcriteria:

OVERALL SUITABILITY FOR ENDORSEMENT

Does the measure meet all the NQF criteria for endorsement? Yes No

Rationale:

If the Committee votes No, STOP.

If the Committee votes Yes, the final recommendation is contingent on comparison to related and competing measures.

5. COMPARISON TO RELATED AND COMPETING MEASURES

If a measure meets the above criteria and there are endorsed or new related measures (either the same measure focus or the same target population) or competing measures (both the same measure focus and the same target population), the measures are compared to address harmonization and/or selection of the best measure before a final recommendation is made.

5.1 If there are related measures (*either same measure focus or target population*) or competing measures (*both the same measure focus and same target population*), list the NQF # and title of all related and/or competing measures:

5a. Harmonization

5a.1 If this measure has EITHER the same measure focus OR the same target population as [NQF-endorsed measure\(s\)](#): Are the measure specifications completely harmonized?

5a.2 If the measure specifications are not completely harmonized, identify the differences, rationale, and impact on interpretability and data collection burden:

5b. Competing Measure(s)

5b.1 If this measure has both the same measure focus and the same target population as NQF-endorsed measure(s): Describe why this measure is superior to competing measures (*e.g., a more valid or efficient way to measure quality*); OR provide a rationale for the additive value of endorsing an additional measure. (*Provide analyses when possible*):

CONTACT INFORMATION

Co.1 Measure Steward (Intellectual Property Owner): [Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Mail Stop S3-01-02, Baltimore, Maryland, 21244-1850](#)

Co.2 Point of Contact: [Thomas, Dudley, Thomas.Dudley@cms.hhs.gov, 410-786-1442-](#)

Co.3 Measure Developer if different from Measure Steward: [Arbor Research/UM-KECC, 340 East Huron St, Suite 300, Ann Arbor, Michigan, 48104](#)

Co.4 Point of Contact: [Claudia, Dahlerus, Claudia.Dahlerus@ArborResearch.org, 734-665-4108-](#)

Co.5 Submitter: [Thomas, Dudley, Thomas.Dudley@cms.hhs.gov, 410-786-1442-](#), [Centers for Medicare & Medicaid Services](#)

Co.6 Additional organizations that sponsored/participated in measure development:

Co.7 Public Contact: [Dahlerus, Claudia.Dahlerus@ArborResearch.org, 734-665-4108-](#), [Arbor Research/UM-KECC](#)

ADDITIONAL INFORMATION

Workgroup/Expert Panel involved in measure development

Ad.1 Provide a list of sponsoring organizations and workgroup/panel members' names and organizations. Describe the members' role in measure development.

[Clinical and data technical expert panels \(TEP\) were held in September and October 2006, respectively. Since 2006, no TEPs have been held for adult hemodialysis adequacy measures.](#)

Ad.2 If adapted, provide title of original measure, NQF # if endorsed, and measure steward. Briefly describe the reasons for

NQF #0247 Hemodialysis Adequacy Clinical Performance Measure I: Hemodialysis Adequacy- Monthly measurement of delivered dose

adapting the original measure and any work with the original measure steward: [No changes to this measure title are requested.](#)

Measure Developer/Steward Updates and Ongoing Maintenance

Ad.3 Year the measure was first released: [2007](#)

Ad.4 Month and Year of most recent revision: [11, 2007](#)

Ad.5 What is your frequency for review/update of this measure? [Every 3 years](#)

Ad.6 When is the next scheduled review/update for this measure? [06, 2013](#)

Ad.7 Copyright statement/disclaimers:

Ad.8 Additional Information/Comments:

Date of Submission (MM/DD/YY): [06/23/2011](#)

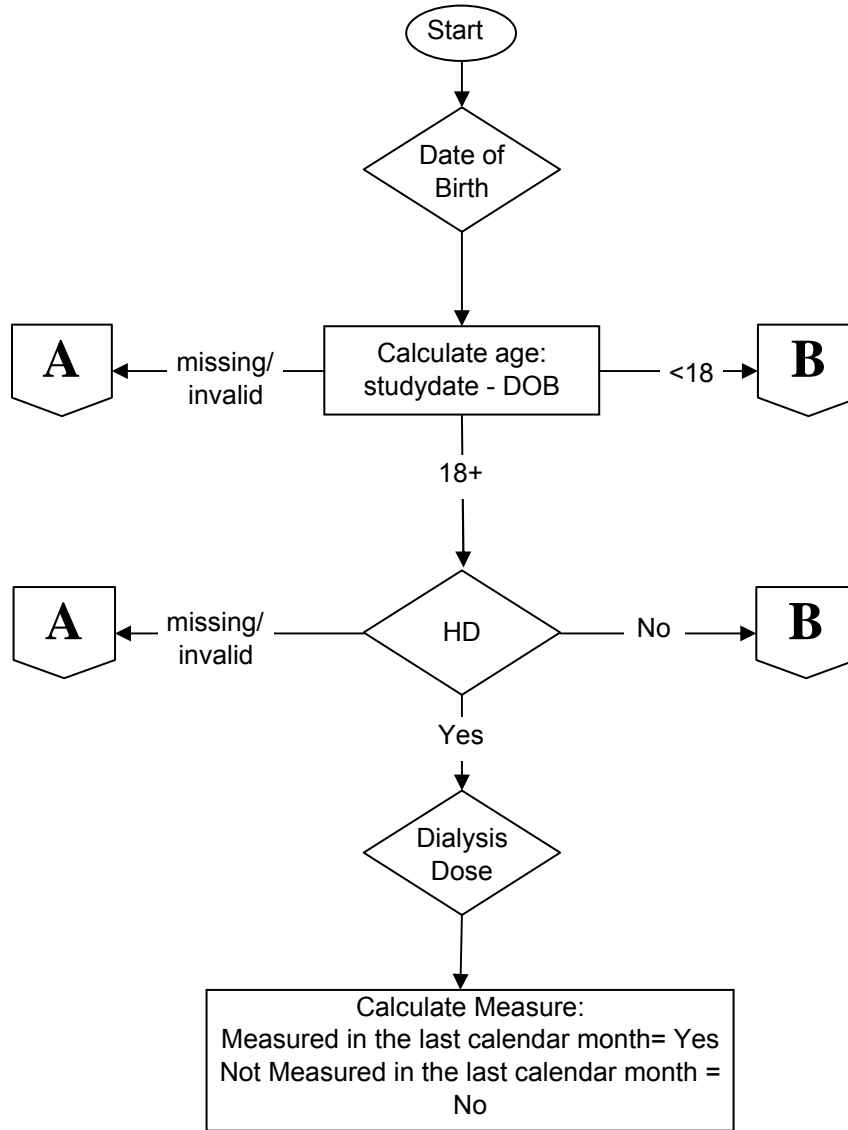
Hemodialysis Adequacy

CPM I: Measurement of Delivered Hemodialysis Dose

Numerator: Percentage of all adult (≥ 18 years old) HD patients in the sample for analyses with documented adequacy measurements (spKt/V) or its components in the calendar month

Denominator: All adult (≥ 18 years old) HD patients.

Exclusion: Pediatric patients. Peritoneal dialysis patients. Acute HD. Transient dialysis patients (<30 days in this center) and kidney transplant patients.



A Excluded due to missing/invalid data

B Exclude for failing to meet inclusion criteria

Technical Notes on the Standardized Mortality Ratio

For the Dialysis Facility Reports

September 2010

**Technical Notes on the Standardized Mortality Ratio
For the Dialysis Facility Reports**

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Introduction

The Standardized Mortality Ratio (SMR) in Table 1 of the Dialysis Facility Reports (DFR) is designed to summarize the mortality at a facility relative to the mortality that would be expected, based on the characteristics of the patients at that facility. The SMR equals the ratio of the actual number of deaths divided by the expected number of deaths. The SMR estimates the relative death rate ratio for a facility, as compared to the national death rate. Qualitatively, the degree to which the facility's SMR varies from 1.00 is the degree to which it exceeds (>1.00) or is under (<1.00) the national death rates for patients with the same characteristics as those in the facility.

An important change to the report this year is that the SMR for a particular calendar year is now compared to the US mortality rates for that same year rather than to the entire 4-year period. The advantage to this is that the reference year for a particular estimate will be the same in each DFR and therefore the SMR value will change less between DFRs. In the past, because these statistics were compared to a different reference population in each DFR, the values changed more over time, even for the same year across reports. The use of a different reference year for each year's estimate will allow you to identify trends over time at your facility beyond the overall US trend over time. In other words, if the SMR for your facility decreases over the time period, this means that mortality at your facility has decreased more over that time period than the overall US average mortality decreased. If mortality at your facility decreased over the four year period at the same rate that overall US mortality decreased over this time period, the SMR for your facility would be the same for each year.

The SMR is adjusted for age, race, ethnicity, sex, diabetes, duration of ESRD, nursing home status, comorbidities at incidence, body mass index (BMI) at incidence, calendar year, and race-specific state population death rates. The SMR indicates whether patients treated in the facility had higher or lower mortality than expected when adjusted for age, race, ethnicity, sex, diabetes, years of ESRD, comorbidities, BMI, year, and population death rates. Quantitatively, if the facility's death rates equal the national death rates (in deaths per patient year or per year at risk) times a multiplicative constant, then the SMR estimates that multiplicative constant. If the multiplicative constant varies for different subgroups of patients, then the SMR estimates a weighted average of those constants according to the facility's patient mix. For example, an $SMR=1.10$ would indicate that the facility's death rates typically exceed national death rates by 10% (e.g., 22 deaths observed where 20 were expected, according to the facility's patient mix). Similarly, an $SMR=0.95$ would indicate that the facility's death rates are typically 5% below the national death rates (e.g., 19 observed versus 20 expected deaths). An $SMR=1.00$ would indicate that the facility's death rates equal the national death rates, on average.

Similarly, the regional SMR values in the DFR are calculated as the ratio of the total number of observed deaths among patients from each region to the number of expected deaths among patients from each region.

Assignment of Patients to Facilities for the SMR Calculation

This section describes the methods we used to assign patients to a facility in order to calculate the SMR. Because some patients receive dialysis treatment at more than one facility in a given year, we use standard methods based on assigning person-years to a facility, rather than on assigning a patient's entire follow-up to a facility. We developed conventions which define the group of patients assigned to a facility at any time during the particular year. This method is described below.

General Inclusion Criteria for Dialysis Patients

A patient's follow-up in the database can be incomplete during the first 90 days of ESRD therapy. For the purposes of this report, we only entered a patient's follow-up into the tabulations after that patient had received chronic renal replacement therapy for at least 90 days. Mortality and survival during the first 90 days do not enter into the calculations. This minimum 90-day period assures that most patients are eligible for Medicare insurance — either as their primary or secondary insurer. It also excludes from analysis patients who died during the first 90 days of ESRD, since such patients may have incomplete data.

In order to exclude patients who only received temporary dialysis therapy, we assigned patients to a facility only after they had been on dialysis there for at least 60 days. This 60 day period is used both for patients who started ESRD for the first time and for those who returned to dialysis after a transplant. That is, deaths and survival during the first 60 days of treatment at a facility do not affect the SMR of that facility.

Identifying Facility Treatment Histories for Each Patient

For each patient, we identified the dialysis provider at each point in time using data from a combination of Medicare-paid dialysis claims, the Medical Evidence Form (Form CMS-2728), and paid dialysis claims. Starting with day 91 of ESRD, we determined facility treatment histories for each patient, and then listed each patient with a facility only once the patient had been treated there for 60 days. When a patient transferred from a facility, the patient remained assigned to it in the database for 60 days. This continued tabulation of the time at risk for 60 days after transfer from a facility attributes to a facility the sequelae of treatment there for 60 days, even when a patient was transferred to another facility (such as a hospital-based facility) after the patient's condition worsened.

In particular, we placed patients in their initial facility on day 91 of ESRD once that facility had treated them for at least 60 days. If on day 91 a facility had treated a patient for fewer than 60 days, we waited until the patient reached day 60 of treatment at that facility before placing him or her there. State and Network summaries do not include patients who were not assigned to a facility; these patients are, however, included in the U.S. summaries.

Using SIMS data and paid dialysis claims to determine whether a patient has transferred to another facility, we attributed patient outcomes to the patient's original facility for 60

days after transfer out. On day 61 after transfer from a facility, we placed the patient in the new facility once s/he had been treated at the new facility for 60 days. When a patient was not treated in a single facility for a span of 60 days (for instance, if there were two switches within 60 days of each other), we did not attribute that patient to any facility.

Patients were removed from a facility's analysis upon receiving a transplant. Patients who withdrew from dialysis or recovered renal function remained assigned to their treatment facility for 60 days after withdrawal or recovery. Additionally, patients for whom the only evidence of dialysis treatment is the existence of Medicare claims were considered lost to follow-up and removed from a facility's analysis one year following the last claim, if there was no earlier evidence of transfer, recovery, or death. In other words, if a period of one year passed with neither paid Medicare dialysis claims nor SIMS information to indicate that a patient was receiving dialysis treatment, we considered the patient lost to follow-up, and did not continue to include that patient in the analysis. If evidence of dialysis re-appeared, the patient was entered into analysis after 60 days of continuous therapy at a single facility. Finally, all SIMS records noting continuing dialysis were extended until the appearance of any evidence of recovery, transfer, or death. Periods of lost to follow-up were not created in these cases since the instructions for SIMS only require checking patient data for continued accuracy, but do not have a requirement for updating if there are not any changes.

Days at Risk for Each Patient

After patient treatment histories are defined as described above, periods of follow-up time are created for each patient. A new time period begins each time the patient is determined to be at a different facility and at the start of each calendar year. The number of days at risk starts over at zero for each time period so that the number of days at risk for any patient-year-facility period is always a number between 0 and 365 (or 366 for leap years). Therefore, a patient who is in one facility for all four years is analyzed the same way as four separate patients in the facility for one year each. When patients are treated at the same facility for two or more separate time periods during a year, the days at risk at the facility is the sum of all time spent at the facility for the year. For example, consider a who patient spends two periods of 100 days assigned to a facility, but is assigned to a different facility for the 165 days between these two 100-day periods. This patient will have one period of 200 days at risk at the first facility, and a separate period of 165 days at risk at the second facility.

The number of days at risk (t_i) in each of these patient-year-facility time periods is used to calculate the expected number of deaths for the patient during that period as described in the "Calculation of Expected Deaths at a Facility" section below. The SMR for a facility is the ratio of the total number of observed to the total number of expected deaths during all time periods at the facility.

Model for Calculating Expected Mortality

The SMR uses expected mortality calculated from a Cox model (SAS Institute Inc., 2004; Andersen, 1993; Collett, 1994). The model is fit in two stages. The stage 1 model is a

Cox model stratified by facility and adjusted for patient age, race, ethnicity, sex, diabetes, duration of ESRD, nursing home status, patient comorbidities at incidence, calendar year, body mass index (BMI) at incidence. This model allows the baseline survival probabilities to vary between strata (facilities), and assumes that the regression coefficients are the same across all strata. The linear predictor for each patient based on the regression coefficients in the stage 1 model is then used as an offset in the stage 2 model, which also includes adjustment for race-specific state population death rate.

The patient characteristics included in the stage 1 model as covariates are age, race, ethnicity, sex, cause of ESRD (diabetes or other), duration of ESRD (<1 year, 1-2 years, 2-3 years, 3+ years as of the period start date), nursing home status, comorbidity index at incidence, calendar year, BMI at incidence, and interaction terms between race, sex and duration and cause of ESRD. Age as of the period start date is included as a piecewise continuous variable with different coefficients based on whether the patient is 0-13 years old, 14-60 years old, or 61+ years old, and whether the patient is black or not. Ethnicity is included with different coefficients for white and non-white patients. The comorbidity index is included as a linear variable. BMI and race-specific state population death rates are included as log-linear terms. Categorical indicator variables are included as covariates in the stage 1 model to flag records missing values for cause of ESRD, comorbidity index, calendar year, and BMI. These variables have a value of 1 if the patient is missing the corresponding piece of information and a value of 0 otherwise. The stage 2 model includes the population death rate for patients of that race in that state as a covariate. The example below shows how these coefficients are used to carry out the calculations.

The Microsoft Excel file available with this document indicates the value of the coefficient for each characteristic in the stage 1 and 2 models (beta) as well as the corresponding standard error and a p-value indicating if the coefficient is significantly different than 0. The file also includes the baseline survival curve for the stage 2 model. The comorbidity index is calculated as a weighted linear combination of comorbidities reported on the Medical Evidence Form (CMS-2728). These weights are also provided in the Excel file.

Age adjusted population death rates (per 100,000) by state and race are obtained from the U.S. Centers for Disease Control National Center for Health Statistics. The 2010 DFR used age-adjusted death rates for 2003-05 from Table 27 of the publication *Health, United States, 2008, With Chartbook on Trends in the Health of Americans* available at <http://www.cdc.gov/nchs/data/hus/hus08.pdf>.

Missing Data

Patients with missing data are not excluded from the model. Patients with missing diagnosis are included in the “other” diagnosis group strata. For the purposes of calculation, missing values for the comorbidity index and BMI are replaced with mean values for patients with similar age, race, sex, and cause of ESRD. When the cause of ESRD is missing, missing values are replaced with mean values for patients with similar age and sex. These mean values are included in the attached tables. Patients with missing race are included in the “other” race group strata and classified as non-White in the

model. Patients with missing ethnicity are classified as “unknown” ethnicity. No patients were missing age, sex, or date of first ESRD treatment.

As mentioned above, indicator variables identifying patients with missing values for cause of ESRD, comorbidity index, and BMI are also included as covariates in the model.

Calculation of Expected Deaths at a Facility

The Cox model consists of two stages. Stage 1 yields estimates of the coefficients β_j for the 42 covariates in the model. Using these coefficients, a predicted value is calculated for each patient. Stage 2 of the model uses only one covariate, the log of the population death rate for the patient’s race within the state, and utilizes the patient’s predicted value from stage 1 as an offset. The predicted value from stage 1 and the baseline survival curve from stage 2 of the Cox model are then used to calculate the expected number of deaths for a specific patient.

Let p denote the number of patient characteristics in the model and x_{ij} be the specific value of the j^{th} characteristic for the i^{th} patient. In stage 1, for patient i , with characteristics

$$\mathbf{X}_i = x_{i1}, x_{i2}, \dots, x_{ip},$$

we calculate:

$$\text{stage 1 } \mathbf{X}_i' \mathbf{B} = \beta_1 x_{i1} + \beta_2 x_{i2} + \dots + \beta_p x_{ip}$$

where β_j is the j^{th} coefficient from the model. For a categorical characteristic, the x_{ij} value is 1 if the patient falls into the category and 0 otherwise.

In stage 2, let x_j be the log of the state population death rate for a specific state and race. We utilize **stage 1 $\mathbf{X}_i' \mathbf{B}$** as an offset to calculate:

$$\text{Stage 2 } \mathbf{X}_i' \mathbf{B} = \beta_1 x_j + \text{stage 1 } \mathbf{X}_i' \mathbf{B}$$

Suppose that t_i is the end of follow-up time for patient i and that $S_{0k_i}(t_i)$ is the baseline survival probability at time t_i . The survival probability for this patient at time t_i is:

$$S_{ik_i}(t_i) = [S_{0k_i}(t_i)]^{\exp(\text{stage 2 } \mathbf{X}_i' \mathbf{B})}$$

The expected number of deaths for this patient during follow-up is then

$$-\ln(S_{ik_i}(t_i)) = -e^{\text{stage 2 } \mathbf{X}_i' \mathbf{B}} \ln[S_{0k_i}(t_i)]$$

and summing these values for the N patients at the facility

$$\sum_{i=1}^N -\ln[S_{ik_i}(t_i)] = -\sum_{i=1}^N e^{\text{stage 2 } \mathbf{X}_i' \mathbf{B}} \ln[S_{0k_i}(t_i)]$$

results in the expected number of deaths during follow-up at the facility. Thus, patients with 100 days of follow-up, who are otherwise the same, have the same expected mortality even if the 100 day period started at different dates during the year. This approximation is made to simplify the calculations.

As stated above, the SMR is the ratio of this expected value to the total number of deaths observed at the facility during follow-up.

Example

As an example, we calculate the one-year SMR for a hypothetical facility in Florida that treated 5 patients in 2008. Table 1 describes the patients and their sequelae of treatment.

Table 1. Description of example patients at example facility for 2008 SMR calculation

Patient	Start of ESRD	Dates treated at this facility	Characteristics
1	4/15/2006	4/15/2006 to 12/31/2008	Male, White, 51, diabetic, alcohol dependence at incidence, BMI=32.2
2	3/1/2008	3/1/2008 to 12/31/2008	Female, Black, 70, BMI=23.0
3	11/1/2007	11/1/2007 to 11/10/2008 death	Female, Black, 78, BMI=22.1
4	8/15/2002	7/15/2008 to 7/31/2008 transfer	Female, Asian, 66, diabetic, Hispanic, BMI=18.7
5	11/1/2003	11/1/2003 to 4/1/2008 transfer and 8/1/2008 to 12/31/2008	Male, 83, missing race and cause of ESRD, COPD at incidence , BMI=28.5

First we determine which patients are assigned to the facility and for how many days each assignment lasts. Patient 1 started treatment at our example facility in 2006 and is assigned to the facility for the entire year of 2008. Patient 2 started renal replacement therapy on 3/1/2008 and is assigned to our facility after 90 days. Patient 3, similarly, started RRT on 11/1/2007 is assigned to our facility after 90 days until her death on 11/10/2008. Patient 4 was only in our facility 16 days, so was never assigned to our facility. Patient 5 started treatment at our facility in 2003 but was treated at another facility from 4/1/2008 through 8/1/2008, so has two treatment periods at the facility which are combined. Table 2 summarizes the assignment periods.

Table 2. Patient assignment periods

Patient	Dates Assigned	Days (t _i)	Notes
1	1/1/2008 to 12/31/2008	366	
2	5/30/2008 to 12/31/2008	216	Eligible starting with day 91 of ESRD
3	1/30/2008 to 11/10/2008	286	Eligible starting with day 91 of ESRD
5	1/1/2008 to 5/31/2008 and 10/1/2008 to 12/31/2008	152+ 92 = 244	Segment 1: Remains assigned to facility for 60 days after transfer out + Segment 2: Eligible starting with day 61 at facility after transfer in

For each patient period, we calculate the **stage 1 X_i'B** using the comorbidity index weights table, the mean values for imputation of comorbidity index and BMI table, and the coefficients table in the Excel file. Table 3 shows these details for the example. Note

the calculations can be affected by rounding. We show only four decimal places for ease of display.

Table 3. Stage 1 Calculations for each patient period

Patient	Comorbidity index	$X_i'\beta^*$	Stage 1 $X_i'\beta$
1	CI=0.3123	(age)(- 0.099) + (age-14)(.129) + (CI)(0.796) + bmi(-0.309) + (vin23)(-.133) + (diab)(.286) + (year2008)(.031)+ (hispanic)(-.369) + (vin23*diab)(-.117)	-1.524
2	CI=0	(age)(- 0.099)+(age-14)(.129)+(age-60)(-.00003)+bmi(-0.309) + (black)(-.351) + (female)(-.061) + (vin01)(-.011) + (year2008)(.031) + (black*female)(.080) + (vin01*black)(.034) + (vin01*female)(.048) + (black*age)(.022) + (black*age-14)(-.029) + (black*age-60)(.008)	-0.884
3	CI=0	(age)(- 0.099) + (age-14)(.129) + (age-60)(-.00003) + bmi(-0.309) + (black)(-.351) + (vin12)(-.186) + (female)(-.061) + (year2008)(.031) + (black*female)(.080) + (black*age)(.022) + (black*age-14)(-.029) + (black*age-60)(.008)	-0.884
5	CI=0.2260	(age)(- 0.099) + (age-14)(.129) + (age-60)(-.00003) + (CI)(0.796) + bmi(-0.309)+(missc)(-.044) + (year2008)(.031) + (unknown)(-.197) + (unknown*nonwhite)(.263)	-0.084

* CI = Comorbidity index, add weights from table in attachment
 bmi = natural logarithm of body mass index
 missc = missing cause of ESRD, 0 for no, 1 for yes

Next we use the **stage 1 $X_i'\beta$** as an offset in step 2 of the model, which includes only the race-specific state population death rate as a covariate.

Table 4. Stage 2 Calculations for each patient period

Patient	$X_i'\beta^*$	Stage 2 $X_i'\beta$
1	(popdrate)(.4165) + Stage 1 $X_i'\beta$	-1.429
2	(popdrate)(.4165) + Stage 1 $X_i'\beta$	1.614
3	(popdrate)(.4165) + Stage 1 $X_i'\beta$	1.732
5	(popdrate)(.4165) + Stage 1 $X_i'\beta$	-0.109

* popdrate = log of the race-specific state population death rate

We also use the Excel file to find the baseline survival probability $S_{0k_i}(t_i)$, by finding the corresponding survival value given the number of days at risk in the patient period.

Table 5 shows these details for the example. Again, note the baseline survival probabilities are shown to four decimal places in this example.

Table 5. Baseline survival values

Patient	Days (t _i)	S _{0k_i} (t _i)
1	365	0.6649
2	216	0.7804
3	285	0.7262
5	244	0.7584

Finally, we calculate $-e^{\text{stage } 2 \text{ } X_i \cdot \beta} \ln[S_{0k_i}(t_i)]$, the expected number of deaths for each of these patients.

Table 6. Calculate expected deaths for each patient

Patient	Stage 2 X _i ·β	$-e^{\text{stage } 2 \text{ } X_i \cdot \beta}$	ln[S _{0k_i} (t _i)]	expected deaths
1	-1.552	-0.212	-0.408	0.086
2	-0.905	-0.405	-0.248	0.100
3	-0.905	-0.405	-0.320	0.129
5	-0.109	-0.897	-0.277	0.248

The total expected number of deaths in this facility for 2008 is the sum of the expected number of deaths for all the patient periods in that facility, or in this case 0.564. Because there was one death in the facility during 2008, the SMR is 1/0.564, or 1.77.

Caveats

Calculation of the SMR using this method may differ from the SMR published in the DFR for several reasons. For example, the DFR includes deaths within 60 days after transfer out of a facility, but this information may not be available to other researchers. Other differences in the calculation of days at risk will affect expected mortality and may be associated with events such as transfer, transplant, withdrawal from dialysis, hospitalization, and loss to follow-up. Differences in the coding of patient characteristics may also cause other researcher’s calculations to differ from those published in the DFR.

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