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 #: 0250 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: ESRD- HD Adequacy CPM III: Minimum Delivered Hemodialysis Dose for ESRD hemodialysis patients undergoing dialytic treatment for a period of 90 days or greater.

Co.1.1 Measure Steward: Centers for Medicare & Medicaid Services

De.2 Brief Description of Measure: Percentage of all adult (>= 18 years old) patients in the sample for analysis who have been on hemodialysis for 90 days or more and dialyzing thrice weekly, and have a residual renal function (if measured in the last three months) less than 2 ml/min/1.73m2), whose delivered dose of hemodialysis (calculated from the last measurements of the month using the UKM or Daugirdas II formula) was a spKt/V >= 1.2 during the reporting period.

2a1.1 Numerator Statement: Number of patients in denominator whose delivered dose of hemodialysis (calculated from the last measurements of the month using the UKM or Daugirdas II formula) was a spKt/V >= 1.2.

2a1.4 Denominator Statement: All adult (>= 18 years old) patients in the sample for analysis who have been on hemodialysis for 90 days or more and dialyzing thrice weekly and whose RRF is unmeasured or whose RRF<2 ml/min/1.73m2 (if measured in the last three months).

2a1.8 Denominator Exclusions: Patients on HD less than 90 days. Patients with RRF >2 ml/min/1.73m2 (measured in the last three months). Patients not in thrice weekly dialysis.

1.1 Measure Type: Outcome
2a1. 25-26 Data Source: Administrative claims
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 (*title and NQF number if endorsed*):

STAFF NOTES (*issues or questions regarding any criteria*)

Comments on Conditions for Consideration:

Is the measure untested? Yes☐ No☐ 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 (*check De.5*):
5. Similar/related endorsed or submitted measures (*check 5.1*):
Other Criteria:

Staff Reviewer Name(s):

1. IMPACT, OPPORTUITY, 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.
Measures must be judged to be important to measure and report in order to be evaluated against the remaining criteria. (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)*:

1a.1 Demonstrated High Impact Aspect of Healthcare: Affects large numbers, 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)*:
The dose of dialysis is used to estimate the ability of hemodialysis to clear the blood of accumulated toxins. In the adult population, outcome studies have shown an association between dose of hemodialysis in terms of small solute removal and clinical outcomes[1,2]. In addition, at least one prior study demonstrates that a change in dialysis dose is associated with a change in patient outcome [3]. Furthermore, studies demonstrate an association between dialysis adequacy as measured by Kt/V and outcomes [4,5,6]. Also, although higher dialysis dose is associated with improvement in clinical outcomes, analysis of CROWNWeb data from January 2010 indicate that only 66% of facilities had 70% or more of their patients receiving a dialysis dose of spKt/V of 1.2.
For this measure maintenance cycle, we propose that this measure remains in its current format. Since endorsement of this measure, published literature suggests there is insufficient evidence that compares methods of dialysis adequacy measurement, particularly measures that demonstrate superiority of alternative measures over spKt/V. It should also be noted that there have been no changes in the KDOQI Clinical Practice Guideline for Methods for Measuring and Expressing Hemodialysis Dose (CPG 2). Indeed, as stated in the KDOQI 2006 update, ´The delivered Kt/V determined by single-pool urea kinetic modeling continues to be preferred as the most precise and accurate measure of dialysis.´ (p.12, KDOQI 2006 Update). Currently, frequent hemodialysis (more than thrice weekly) is still rare, with approximately 1% of dialysis patients receiving this modality. As this population grows and the evidence base for alternative adequacy measurement methods grows, the use of
stdKt/V, in particular should be evaluated by a Clinical Technical Expert Panel (CTEP), including a target measure because of the potential for a growing percentage of patients being dialyzed more than thrice weekly and where spKt/V is not comparable across treatment schedules. Additional considerations for future expert review of the use of spKt/V measure relates to women and smaller patients. Recent studies that examine dialysis dosing in women and smaller patients should be considered [7,8]. In addition, because prior studies that evaluate the impact of hemodialysis dose on mortality have used spKt/V as the measure of hemodialysis adequacy, alternative methods of adequacy measurement should also be considered. Finally, recent clinical studies suggest the benefit of using online measurement methods for assessing ionic clearance, and these tools should be considered in the future [9]. Another point to be considered with this measure is the requirement for a 3 month duration of HD with documentation that residual renal function (RRF) is less than 2ml//min/1.73m2 prior to inclusion. This is in contrast to a related endorsed measure which requires a 6 month duration of HD and does not take into account RRF. The differentiation between these two measures is related to 2 clinical possibilities: the first is that patients that start HD may have RRF, and second, that measurement of this RRF is not necessarily standard practice. Currently data measuring RRF in HD patients are not readily available, but RRF is a planned data element in the future.

1a.4 Citations for Evidence of High Impact cited in 1a.3: 1. Lowrie EG, et al. Effect of the hemodialysis prescription of patient morbidity:report from the National Cooperative Dialysis
Study. N Engl J Med 305:1176–1181, 1981.
2. Owen WF Jr, et al. The urea reduction ratio and serum albumin concentration as predictors of mortality in patients undergoing hemodialysis. N Engl J Med 329:1001–1006, 1993.
3. 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.

4. 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.
5. 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.
6. 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.
7. Daugirdas JT, Greene T, Chertow GM, et al. Can Rescaling Dose of Dialysis to Body Surface Area in the HEMO Study Explain the Different Responses to Dose in Women versus Men? Clin J Am Soc Nephrol. 2010 Sep;5(9):1628-36.
8. Daugirdas JT, Hanna MG, Becker-Cohen R, et al. Dose of dialysis based on body surface area is markedly less in younger children than in older adolescents. Clin J Am Soc Nephrol. 2010 May;5(5):821-7.
9. Lowrie EG, Li Z, Ofsthun NJ, et al. Evaluating a new method to judge dialysis treatment using online measurements of ionic clearance. Kidney Int. 2006 Jul;70(1):211-7.

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:
Published studies indicate there is an association between low spKt/V and increased mortality. Furthermore, the 2006 KDOQI Hemodialysis Adequacy Guidelines indicate ´minimally adequate dose of HD given 3 times per week to patients with Kr less than 2 mL/min/1.73 m2 should be an spKt/V of 1.2 per dialysis.´

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.*]
Currently data measuring RRF in HD patients are not readily available, but reporting of RRF will be implemented in future releases of CROWNWeb.

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*]
Please see 1b.2.

1b.4 Summary of Data on Disparities by Population Group: [*For Maintenance –Descriptive statistics for performance results for this measure by population group*]
Please see 1b.2.

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*]
Please see 1b.2.

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☐
L	M-H	M	Yes☐ IF additional research unlikely to change conclusion that benefits to patients outweigh harms: otherwise No☐
M-H	L	M-H	Yes☐ IF potential benefits to patients clearly outweigh potential harms: otherwise No☐
L-M-H	L-M-H	L	No ☐

Health outcome – rationale supports relationship to at least one healthcare structure, process, intervention, or service	Does the measure pass subcriterion1c? Yes☐ IF rationale supports relationship

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 measurement of spKt/V >= 1.2.
This process leads to improvement in mortality as follows:
Measure spKt/V--> Assess value-->Impact on mortality.

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

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 is a target measure for spKt/V below which a higher risk for adverse outcomes is observed. The evidence is directly related to this measure.

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. Thus, this evidence directly supports this measure. Of the 11 studies, 5 measured dialysis dose using spKt/v [1,3,8,9,10], and 3 used URR[4,5,7]. The remaining studies used eKt/V [2,6]. Among the studies using spKt/V, one study was a randomized clinical trial (HEMO study) with 1846 patients, one was a prospective study with 740 patients, and the remaining were retrospective cohort studies with sample sizes of 1771 and 1151. Two of these studies found a significant improvement in mortality with increasing dose of spKt/V. The remaining study compared higher doses of spKt/v to the standard dose (spKt/V =1.2) and found higher doses did not improvement in mortality compared to the standard dose. Of the three studies measuring URR, 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.

1c.7 Consistency of Results across Studies *(Summarize the consistency of the magnitude and direction of the effect):* Results were consistent across studies. Four studies measuring adequacy using spKt/V [3,8,9,10] and two measuring URR found higher doses were associated with lower mortality [4,5]. The remaining studies found that increasing dose above the standard dose did not improve mortality.

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 with increasing dose of spKt/V, relative risks (RR) were presented as spKt/V per increase of 1 unit and spKt/V per 0.1 unit, where spKt/V was analyzed as a continuous measure. The RR per 1 unit increase in spKt/V was 0.76 (95% CI: 0.64, 0.92; p=0.004) [3], and per 0.1 unit increase in spKt/V was 0.95; p<0.05 (no CI given) [8]. The HEMO trial found no significant difference in mortality among patients in the high dose group, with mean = 1.56 and SD=0.09, compared to the low dose group with mean=1.16 and SD=0.08 (RR=0.96; 95% CI: 0.84, 1.10) [1], thus supporting the current target spKt/V of 1.2. However, a subgroup analysis of the HEMO study [2] showed that survival rates in women randomized to the higher dose group were higher than women in the lower dose group (relative risk 0.81; p = 0.02) and this association
persisted after adjusting for body size.
In the remaining study, findings showed patients receiving the highest dialysis dose(spKt/V>2.4) compared to the standard dose group (spKt/V 1.2-1.3) had an increased risk of mortality (RR=2.5; p<0.05), although this may be suggestive of confounding by indication. No other significant associations between dose groups were found in this study [9].

All but one study showed a benefit for a minimum dose of dialysis when measured as spKt/V. Studies evaluating higher doses of dialysis adequacy did not demonstrate additional benefit at spKt/V doses higher than the current target of 1.2. The increase in mortality at the highest dialysis dose is thought to be due to confounding by indication and does not suggest that higher dialysis dose is associated with increased mortality.

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, 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, but individual studies were graded as above.

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. 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.
3. 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.
4. 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.
5.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.
6. 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.
7. 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.
8. Leypoldt JK, Cheung AK, Carroll CE, et al: Effect of dialysis membranes and middle molecule removal on chronic hemodialysis patient survival. Am J Kidney Dis 33:349-355, 1999.
9. 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.
10. Woods HF, Nandakumar M: Improved outcome for haemodialysis patients treated with high-flux membranes. Nephrol Dial Transplant 15:S36-S42, 2000 (suppl 1).

1c.16 Quote verbatim, the specific guideline recommendation *(Including guideline # and/or page #)*:
Clinical Practice Guidelines for Hemodialysis Adequacy
GUIDELINE 4. MINIMALLY ADEQUATE HEMODIALYSIS
The minimally adequate dose of HD given 3 times per week to patients with Kr less than 2 mL/min/1.73 m2 should be an spKt/V (excluding RKF) of 1.2 per dialysis. For treatment times less than 5 hours, an alternative minimum dose is a URR of 65%. (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. No information on representation of disclosures regrading bias.

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: High1c.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 denominator whose delivered dose of hemodialysis (calculated from the last measurements of the month using the UKM or Daugirdas II formula) was a spKt/V >= 1.2.

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*:

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

All adult (>= 18 years old) patients in the sample for analysis who have been on hemodialysis for 90 days or more and dialyzing thrice weekly and whose RRF is unmeasured or whose RRF<2 ml/min/1.73m2 (if measured in the last three months).

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)*:

2a1.8 Denominator Exclusions *(Brief narrative description of exclusions from the target population)*:
Patients on HD less than 90 days. Patients with RRF >2 ml/min/1.73m2 (measured in the last three months). Patients not in thrice weekly dialysis.

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)*:

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)*:

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.)*:

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.

2a1.21-23 Calculation Algorithm/Measure Logic Diagram URL or attachment:
Attachment
Appendix C CPM Calculation Flow charts_a 6.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):

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

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://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)*:
Reliability testing could not be performed for this measure since data measuring RRF in HD patients are not available. Reporting of RRF will be implemented in future releases of CROWNWeb.

2a2.2 Analytic Method *(Describe method of reliability testing & rationale)*:
Not applicable.

2a2.3 Testing Results *(Reliability statistics, assessment of adequacy in the context of norms for the test conducted)*:
Not applicable.

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:
Please see 2a2.1.

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)*:
Not applicable.

2b2.2 Analytic Method *(Describe method of validity testing and rationale; if face validity, describe systematic assessment)*:
Not applicable.

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)*:
Not applicable.

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)*:
Exclusion analyses could not be performed for this measure since data measuring RRF in HD patients are not available. Reporting of RRF will be implemented in future releases of CROWNWeb.

2b3.2 Analytic Method (*Describe type of analysis and rationale for examining exclusions, including exclusion related to patient preference)*:
Not applicable.

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 adjustments are necessary for this measure.

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: Not applicable.

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 could not be performed for this measure since data measuring RRF in HD ptients are not available. Reporting of RRF will be implemented in future releases of CROWNWeb.

2b5.2 Analytic Method *(Describe methods and rationale to identify statistically significant and practically/meaningfully differences in performance)*:
Not applicable.

2b5.3 Results *(Provide measure performance results/scores, e.g., distribution by quartile, mean, median, SD, etc.; identification of statistically significant and meaningfully differences in performance)*:
Not applicable.

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)*: Not applicable.

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

2.1-2.3 Supplemental Testing Methodology Information:

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

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 be evaluated for future public reporting on Medicare's Dialysis Facility Compare website and for Dialysis Facility Reports.

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: This measure has been reported in previous ESRD CPM Annual Reports. Healthcare providers and patients can easily understand the meaning of this measure. In addition, there is general acceptance by the Nephrology community of the use of spKt/V for the

measurement of dialysis adequacy. Clinical practice guidelines further support this measure. The percent of patients with monthly adequacy measurements improved from 85% in 1998 to 94% 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, with a target of 1.2, 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.

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*].
The use of spKt/V to measure dialysis adequacy has been used in multiple quality improvement programs. An example is an initative 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 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:
This measure has not been tested since RRF is not collected in the available CROWNWeb data. Reporting of RRF will be implemented in future releases of CROWNWeb. Once all data elements for this measure are available in CROWNWeb, there are no anticipated data 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)*:
Testing of this measure has not been performed.

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: Claudia, 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 (TEPs) 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 adapting the original measure and any work with the original measure steward: No changes to this measure 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

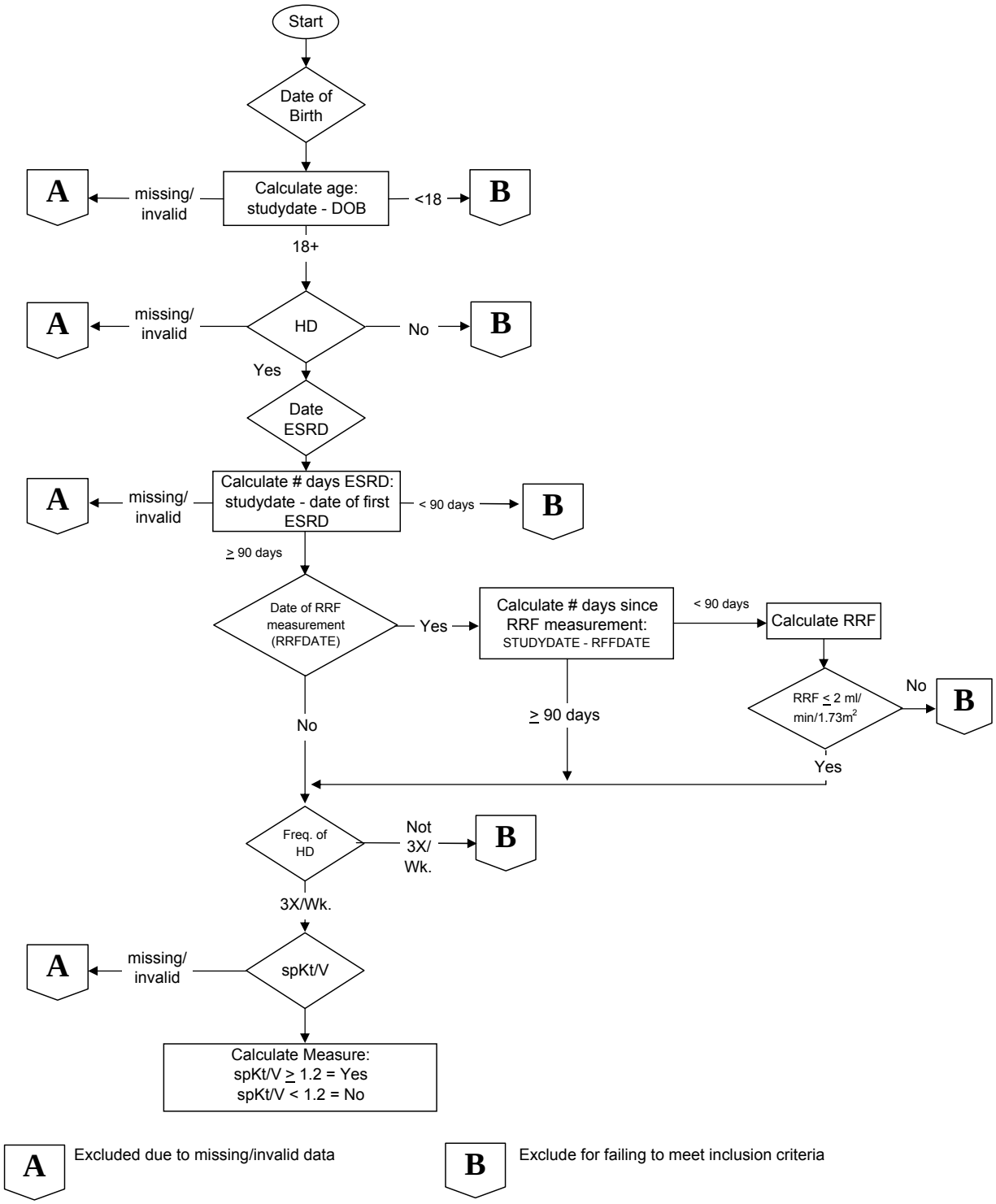
Hemodialysis Adequacy

CPM III.b: Minimum Delivered Hemodialysis Dose

Numerator: Number of patients in the denominator whose delivered dose of hemodialysis (calculated from last measurements of the month *using the UKM or Daugirdas II formula)* was a spKt/V > 1.2 during the study period

Denominator: All adult HD patients (≥ 18 years old) in the sample for analysis who have been on hemodialysis for 90 days or more and dialyzing thrice weekly and whose RRF is unmeasured or whose RRF < 2 ml/min/1.73m^2 (if measured in the last 3 months)

Exclusion: Pediatric patients, peritoneal dialysis patients, acute HD, transient dialysis patients (<30 days in this center), kidney transplant patients, patients with ESRD less than 90 days, patients whose RRF is > 2 ml/min/1.73m^2 (if measured in the last 3 months), patients not on 3x/wk HD



A Excluded due to missing/invalid data

B Exclude for failing to meet inclusion criteria