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 #: 0254 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: Peritoneal Dialysis Adequacy Clinical Performance Measure II - Calculate Weekly KT/Vurea in the Standard Way

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

De.2 Brief Description of Measure: Percentage of all adult (>= 18 years old) peritoneal dialysis patients with weekly Kt/V urea (endogenous residual renal urea clearance & dialytic) calculated in a standard way.

2a1.1 Numerator Statement: Patients with:
(1) Weekly Kt/Vurea used to measure delivered peritoneal dialysis dose and endogenous renal urea clearance;
(2) Residual renal function (unless negligible [< 100mL urine in 24 hours]) assessed by measuring the renal component of Kt/Vurea and estimating the patient´s glomerular filtration rate (GFR) by calculating the mean of urea and creatinine clearance;
(3) Total body water (V) estimated by either the Watson or Hume method using actual body weight, and BSA estimated by either the Dubois and Dubois method, the Gehan and George method, or the Haycock method of using actual body weight;
during the four month study period.

2a1.4 Denominator Statement: All adult (>= 18 years old) peritoneal dialysis patients.

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 (*title and NQF number if endorsed*):
0253 : Peritoneal Dialysis Adequacy Clinical Performance Measure I - Measurement of Total Solute Clearance at Regular Intervals
0318 : Peritoneal Dialysis Adequacy Clinical Performance Measure III - Delivered Dose of Peritoneal Dialysis Above Minimum

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)*: 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)*:
There were 26,517 end-stage renal disease (ESRD) patients being treated with PD at the end of 2008 with approximately 6,577 incident ESRD patients starting peritoneal dialysis each year (USRDS 2010 ADR). KDOQI and European guidelines have set minimum standards for periodic assessment of peritoneal dialysis adequacy (KDOQI 2006; EBPG 2005; Lo 2006). Both peritoneal clearance and residual renal function (RRF) need to be assessed. Both guidelines and studies have emphasized the importance of total clearance.

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. KDOQI Clinical Practice Guidelines and Clinical Practice Recommendations for 2006 Updates: Hemodialysis Adequacy, Peritoneal Dialysis Adequacy and Vascular Access. Am J Kidney Dis 48:S1-S322, 2006 (suppl 1).
3. European Best Practice Guidelines for Peritoneal Dialysis. Adequacy of peritoneal dialysis. Nephrol Dial Transplant 2005; 20 [Suppl 9]: ix24–ix27
4. Lo WK, Bargman JM, Burkart J, et al. Guideline on targets for solute and fluid removal in adult patients on chronic peritoneal dialysis. Perit Dial Int 2006;26:520–522.

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:
Evaluation of PD adequacy every four months in a standard way is critical to ensure timely dose adjustment as needed. Less frequent measurements may compromise the timeliness with which deficiencies in the delivered dose of PD are detected and hence may delay implementation of corrective action. Therefore, continued implementation of this measure is needed to ensure frequent and appropriate 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 mean percentage of patients with PD adequacy measured in a standard way at least once in four months was 34% (SD=30%). Distribution: Min=0%, Max=100%, 1st quartile=0%, median=33%, 3rd quartile=57%. These results indicate that on average, facilities are not measuring total solute clearance for urea at least every four months in 66% of PD patients.

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*]
CROWNWeb performance gap analyses used 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*]
Facilities in the highest quintile of % female had lower performance on the measure (22.1 versus 27.5; p<0.01). Facilities in the highest quintile of % Black had lower performance on the measure (20.6 vs. 25.4; p=0.02). Facilities in the highest quintile of % Asian had higher performance on the measure (27.7 vs. 22.1; p<0.01). There were no other disparities noted in the data.

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 - December 2009 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☐
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 the process of measuring peritoneal dialysis adequacy in a standard way every four months for ESRD dialysis patients. This process leads to improvement in mortality as follows: Measure PD adequacy-->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 clearance and patient survival. This measure focus is on the frequency of measuring peritoneal dialysis adequacy.

1c.5 Quantity of Studies in the Body of Evidence *(Total number of studies, not articles)*: 20.

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 KDOQI panel noted that the body of evidence shows a correlation between total solute clearance for urea and patient mortality and morbidity. Thus, this evidence supports the present measure in that that the delivered dose of dialysis should be measured frequently and in a standard way for

assessment of adequate treatment.
In particular, of the 20 studies considered in the body of evidence, the results from two randomized clinical trials were used to justify the KDOQI guidelines (Paniagua 2002; Lo 2003). The results from additional observational studies also supported the KDOQI recommendations (see, e.g., Bargman 2001; Rocco 2000; Churchhill 1998).

1c.7 Consistency of Results across Studies *(Summarize the consistency of the magnitude and direction of the effect):* Results were consistent across studies in direction, although magnitude varied. Of the 20 studies reviewed by the KDOQI panel, 17 examined either peritoneal clearance or total urea Kt/V. Of these 17 studies, 12 found lower mortality for higher PD clearance; on the other hand, only two noted higher mortality with higher PD clearance, and neither result achieved statistical significance.

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 any improvement in mortality in high total clearance versus low total clearance, relative risks ranged from 0.6 to 0.99. In one study, Kt/V was measured as continuous and found a relative risk of 0.94 per 0.1 mL/min increase in Kt/V (95% CI = 0.88, 1.02). The majority of the studies showed a benefit of higher total clearance in PD patients. Furthermore, there is little or no potential harm in assessing total urea Kt/V for PD patients.

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 KDOQI panel graded the body of evidence level "B".

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: The KDOQI panel assigned a grade of "B" to the body of evidence supporting the related guideline.

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. Bargman JM, Thorpe KE, Churchill DN: Relative contribution of residual renal function and peritoneal clearance to adequacy of dialysis: A reanalysis of the CANUSA Study. J Am Soc Nephrol 12:2158-2162, 2001
2. Paniagua R, Amato D, Vonesh E, et al: Effects of increased peritoneal clearances on mortality rates in peritoneal dialysis: ADEMEX, a prospective, randomized, controlled trial. J Am Soc Nephrol 13:1307-1320, 2002
3. Lo WK, Ho YW, Li CS, et al: Effect of Kt/V on survival and clinical outcome in CAPD patients in a randomized prospective study. Kidney Int 64:649-656, 2003
4. Szeto CC, Wong TY, Leung CB, et al: Importance of dialysis adequacy in mortality and morbidity of Chinese CAPD patients. Kidney Int 58:400-407, 2000
5. Diaz-Buxo JA, Lowrie EG, Lew NL, Zhang SM, Zhu X, Lazarus JM: Associates of mortality among peritoneal dialysis patients with special reference to peritoneal transport rates and solute clearance. Am J Kidney Dis 33:523-534, 1999
6. Rocco MV, Frankenfield DL, Prowant B, Frederick P, Flanigan MJ: Risk factors for early mortality in U.S. peritoneal dialysis patients: Impact of residual renal function. Perit Dial Int 22:371-379
7. Termorshuizen F, Korevaar JC, Dekker FW, van Manen JG, Boeschoten EW, Krediet RT: The relative importance of residual renal function compared with peritoneal clearance for patient survival and quality of life: An analysis of the Netherlands Cooperative Study on the Adequacy of Dialysis (NECOSAD)-2. Am J Kidney Dis 41:1293-1302, 2003
8. Chung SH, Heimburger O, Stenvinkel P, Qureshi AR, Lindholm B: Association between residual renal function, inflammation and patient survival in new peritoneal dialysis patients. Nephrol Dial Transplant 18:590-597, 2003
9. Jager KJ, Merkus MP, Dekker FW, et al: Mortality and technique failure in patients starting chronic peritoneal dialysis: Results of The Netherlands Cooperative Study on the Adequacy of Dialysis. NECOSAD Study roup. Kidney Int 55:1476-1485, 1999
10. Ates K, Nergizoglu G, Keven K, et al: Effect of fluid and sodium removal on mortality in peritoneal dialysis patients. Kidney Int 60:767-776, 2001

11. Wang AY, Wang M, Woo J, et al: Inflammation, residual kidney function, and cardiac hypertrophy are interrelated and combine adversely to enhance mortality and cardiovascular death risk of peritoneal dialysis patients. J Am Soc Nephrol 15:2186-2194, 2004
12. Szeto CC, Wong TY, Chow KM, Leung CB, Law MC, Li PK: Independent effects of renal and peritoneal clearances on the mortality of peritoneal dialysis patients. Perit Dial Int 24:58-64, 2004
13. Szeto CC, Wong TY, Chow KM, et al: Impact of dialysis adequacy on the mortality and morbidity of anuric Chinese patients receiving continuous ambulatory peritoneal dialysis. J Am Soc Nephrol 12:355-360, 2001
14. Bhaskaran S, Schaubel DE, Jassal SV, et al: The effect of small solute clearances on survival of anuric peritoneal dialysis patients. Perit Dial Int 20:181-187, 2000
15. Rocco M, Soucie JM, Pastan S, McClellan WM: Peritoneal dialysis adequacy and risk of death. Kidney Int 58:446-457, 2000
16. Lo WK, Tong KL, Li CS, et al: Relationship between adequacy of dialysis and nutritional status, and their impact on patient survival on CAPD in Hong Kong. Perit Dial Int 21:441-447, 2001
17. Davies SJ, Phillips L, Russell GI: Peritoneal solute transport predicts survival on CAPD independently of residual renal function. Nephrol Dial Transplant 13:962-968, 1998
18. Perez RA, Blake PG, Spanner E, et al: High creatinine excretion ratio predicts a good outcome in peritoneal dialysis patients. Am J Kidney Dis 36:362-367, 2000
19. Park HC, Kang SW, Choi KH, Ha SK, Han DS, Lee HY: Clinical outcome in continuous ambulatory peritoneal dialysis patients is not influenced by high peritoneal transport status. Perit Dial Int 21:S80-S85, 2001 (suppl 3)
20. Aslam N, Bernardini J, Fried L, Piraino B: Peritoneal dialysis clearance can replace residual renal function. Perit Dial Int 21:263-268, 2001

1c.16 Quote verbatim, the specific guideline recommendation *(Including guideline # and/or page #)*:
GUIDELINE 2. PERITONEAL DIALYSIS SOLUTE CLEARANCE TARGETS AND MEASUREMENTS
Data from RCTs suggested that the minimally acceptable small-solute clearance for PD is less than the prior recommended level of a weekly Kt/Vurea of 2.0. Furthermore, increasing evidence indicates the importance of RKF as opposed to peritoneal small-solute clearance with respect to predicting patient survival. Therefore, prior targets have been revised as indicated next.
2.1 For patients with RKF (considered to be significant when urine volume is > 100 mL/d):
2.1.1 The minimal "delivered" dose of total small-solute clearance should be a total (peritoneal and kidney) Kt/Vurea of at least 1.7 per week. (B) 2.1.2 Total solute clearance (residual kidney and peritoneal, in terms of Kt/Vurea) should be measured within the first month after initiating dialysis therapy and at least once every 4 months thereafter. (B)
2.1.3 If the patient has greater than 100 mL/d of residual kidney volume and residual kidney clearance is being considered as part of the patient´s total weekly solute clearance goal, a 24-hour urine collection for urine volume and solute clearance determinations should be obtained at a minimum of every 2 months. (B) 2.2 For patients without RKF (considered insignificant when urine volume is =100 mL/d):
2.2.1 The minimal "delivered" dose of total small-solute clearance should be a peritoneal Kt/Vurea of at least 1.7 per week measured within the first month after starting dialysis therapy and at least once every 4 months thereafter. (B)

1c.17 Clinical Practice Guideline Citation: KDOQI Clinical Practice Guidelines and Clinical Practice Recommendations for 2006 Updates: Hemodialysis Adequacy, Peritoneal Dialysis Adequacy and Vascular Access. Am J Kidney Dis 48:S1-S322, 2006 (suppl 1).

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 regarding 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: B

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)*:
Patients with:
(1) Weekly Kt/Vurea used to measure delivered peritoneal dialysis dose and endogenous renal urea clearance;
(2) Residual renal function (unless negligible [< 100mL urine in 24 hours]) assessed by measuring the renal component of Kt/Vurea and estimating the patient´s glomerular filtration rate (GFR) by calculating the mean of urea and creatinine clearance;
(3) Total body water (V) estimated by either the Watson or Hume method using actual body weight, and BSA estimated by either the Dubois and Dubois method, the Gehan and George method, or the Haycock method of using actual body weight;
during the four month study period.

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

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 met the three criteria indicated in the numerator statement (2a1.1).

2a1.4 Denominator Statement *(Brief, narrative description of the target population being measured)*:
All adult (>= 18 years old) peritoneal dialysis patients.

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)*:

A four month time period.

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)*:
A patient´s age will be determined by subtracting the patient´s date of birth from the first day of the reporting month. Peritoneal dialysis patients are defined as follows: (1) "Admit Date" to the specified facility is prior or equal to the first day of the study period; (2) the patient has not been discharged (i.e., the discharge date is null or blank or the discharge date is greater than or equal to the last day of the study period); (3) the treatment start date is less than or equal to the date of the study period; (4) the type of dialysis treatment = ´PD´; (5) the primary dialysis setting is "Home" or "Dialysis Facility/Center"; (6) the "Date Regular Chronic Dialysis Began" is prior to the first day of the study period.
The denominator will include all patients >= 18 years old who are PD patients assigned to a single facility for a four month period.

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)*:
Not applicable.

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.)*:
None.

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.)*:
The measure is calculated by dividing the number of patients in the numerator by the number of patients in the denominator.

2a1.21-23 Calculation Algorithm/Measure Logic Diagram URL or attachment:
Attachment
PD_CPM2_Flowchart.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):
Not applicable.

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 Phase II (with Test Batch Submissions) data from July 2009-December 2009 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 August 2009 through October 2010.

2a2.3 Testing Results *(Reliability statistics, assessment of adequacy in the context of norms for the test conducted)*:
Correlation coefficients ranged from 0.78 to 0.91. This indicates 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 PD 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 regresion 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%
Q2:0%-3%
Q3:3%-31%
Q4:31%-48%
Q5:48%-100%
Results from the Poisson model indicated lower performance scores were associated with SMR (p=0.04). For Q1, RR=1.04; 95% CI: (0.99, 1.09). For Q2, RR=1.10; 95% CI: (1.04, 1.17). For Q3, RR=1.04, 95% CI: (0.99, 1.10). For Q4, RR=1.05, 95% CI: (1.00, 1.11).

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)*:
There are no patients excluded from this measure.

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 adjustment is performed 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: Although some small disparities by population group were observed (see results in Section 1b.4) there is no evidence suggesting that these disparities are endemic and that the 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):
Please refer to 1b.3 for information on the sample used for performance gap analyses.

2b5.2 Analytic Method *(Describe methods and rationale to identify statistically significant and practically/meaningfully differences in performance)*:
Please refer to 1b.2 for information on the analytic methods used for performance gap analyses.

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)*:
Please refer to 1b.2 for results of the analyses of performance gap.

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, however the measure may be displayed separately for population groups as needed.

2c.2 If disparities have been reported/identified (e.g., in 1b), but measure is not specified to detect disparities, please explain:
Although some small disparities by population group were observed in our analyses (see results in Section 1b.4) there is no published evidence suggesting that these disparities are endemic.

2.1-2.3 Supplemental Testing Methodology Information:
URL
http://www.dialysisreports.org/pdf/esrd/public/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

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.

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, as demonstrated in current performance data presented in the ESRD CPM Annual Reports.

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): This measure is not used for other Accountability Functions.

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*].
This measure is not currently used in a quality improvement program. However,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:
generated by and used by healthcare personnel during the provision of care, e.g., blood pressure, lab value, medical condition

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, 734-665-4108-9366
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: ESRD Quality Measures, Help Desk, ESRD_Quality_Measures@ArborResearch.org, 877-665-1680-, Arbor Research Collaborative for Health

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 peritoneal 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 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

Peritoneal Dialysis Adequacy

CPM 11: Calculate Weekly Kt/V_{urea} in the Standard Way

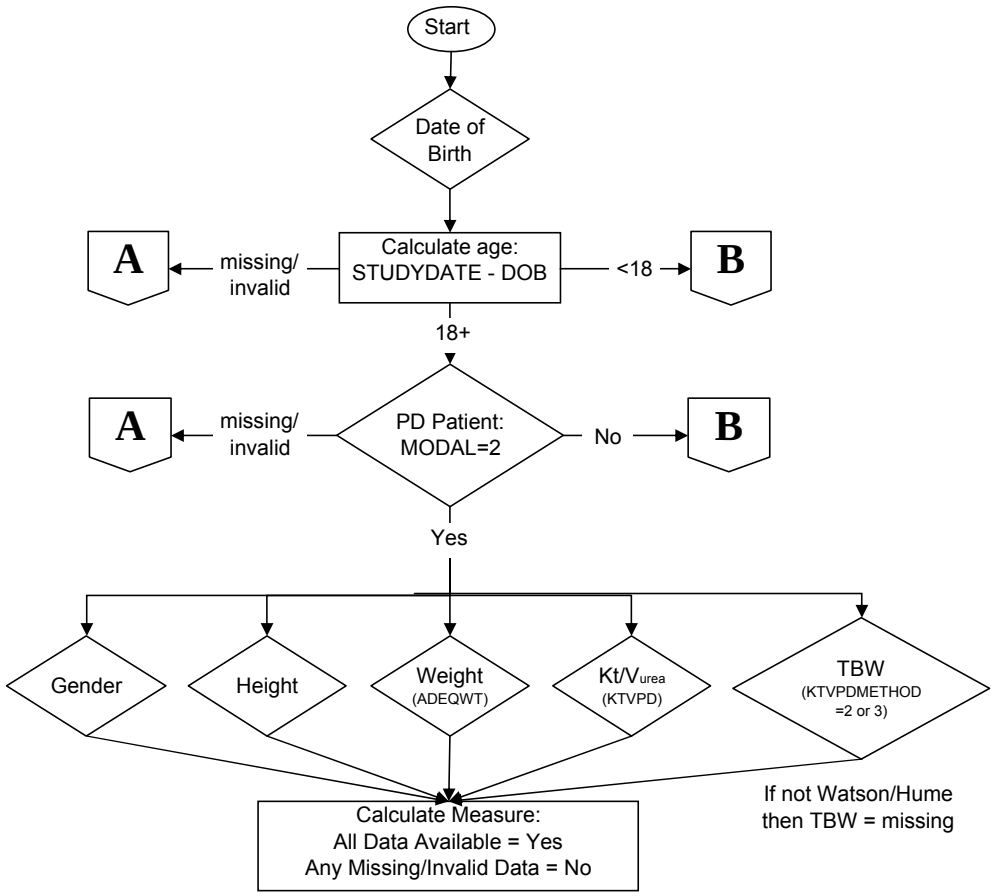
Numerator: Patients with:

* Weekly Kt/V_{urea} used to measure delivered peritoneal dialysis dose and endogenous renal urea clearance
* Residual renal function (unless negligible [<100 mL urine in 24 hours]) is assessed by measuring the renal component of Kt/V_{urea} and estimating the patient's glomerular filtration rate (GFR) by calculating the mean of urea and creatinine clearance
* Total body water (V) estimated by either the Watson or Hume method using actual body weight, and BSA estimated by either the Dubois and Dubois method, the Gehan and George method or the Haycock method using actual body weight,

during the four month study period.

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

Exclusion: Pediatric patients. Hemodialysis patients. Transient dialysis patients,kidney transplant patients.



A Excluded due to missing/invalid data

B Exclude for failing to meet inclusion criteria