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 #: 0323   **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: Solute
Co.1.1 Measure Steward: American Medical Association - Physician Consortium for Performance Improvement
De.2 Brief Description of Measure: Percentage of calendar months within a 12-month period during which patients aged 18 years and older with a diagnosis of ESRD receiving hemodialysis three times a week have a spKt/V > or = 1.2
2a1.1 Numerator Statement: Calendar months during which patients have a spKt/V > or = 1.2   Note: Urea kinetic modeling (UKM) or the second generation Daugirdas formula (simplified multivariable equation) are the most appropriate ways to calculate spKt/V, and the two accepted methods for calculating spKt/V per the KDOQI guidelines. For more information on these methods, please refer to National Kidney Foundation's 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).
2a1.4 Denominator Statement: All calendar months during which patients aged 18 years and older with a diagnosis of ESRD are receiving hemodialysis three times a week
2a1.8 Denominator Exclusions: Documentation of medical reason(s) for patient not having a spKt/V > or = 1.2 (eg, patient has residual kidney function, other medical reasons)
1.1 Measure Type: Outcome   **2a1. 25-26 Data Source:** Administrative claims, Electronic Clinical Data, Electronic Clinical Data : Electronic Health Record, Electronic Clinical Data : Registry, Paper Records   **2a1.33 Level of Analysis:** Clinician : Group/Practice, Clinician : Individual, Clinician : Team   **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*):   This measure is not a composite or paired measure.

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, 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.
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, Renal : End Stage Renal Disease (ESRD)
De.5 Cross Cutting Areas (*Check all the areas that apply*): Safety, Safety : Complications

1a.1 Demonstrated High Impact Aspect of Healthcare: Affects large numbers, A leading cause of morbidity/mortality, Frequently performed procedure, High resource use, Patient/societal consequences of poor quality, Severity of illness

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

1a.3 Summary of Evidence of High Impact (*Provide epidemiologic or resource use data*):
Chronic kidney disease (CKD), affects approximately 13.1% of United States adults and leads to end-stage renal disease (ESRD), cardiovascular disease (CVD), and premature death. (1)

CKD affects up to 5% of the population and 25% of those aged 70 years or older. An additional 6% of the population has signs of kidney damage, which may progress to ESRD. (2)

CKD is not recognized as a major public health concern. It is estimated that approximately 26.3 million adutls in the U.S. have non-dialysis dependent kidney disease and over 470,000 have ESRD, collectively representing over 13% of the US population. In the next 20 years, the burnden of CKD is expected to increase, with over 2 million individuals projected to be receiving renal replacement therapy (dialysis or kidney transplant) by 2030. (3)

Costs for CKD patients are now 23 percent of Medicare expenditures in the fee-for-service sector; when added to costs for ESRD patients, it appears that 31 percent of all Medicare expenditures are incurred by patients with a diagnosis of kidney disease. (4)

The CPM Project report is a summary of a national survey of the quality of care of randomly sampled ESRD patients from each Network, and it is the starting point for Network quality improvement activity. The first CPM report in 1994 found that 43% of all hemodialysis patients nationally and 32% of patients in Network 6 were adequately dialyzed.(5)

1a.4 Citations for Evidence of High Impact cited in 1a.3: 1. Snyder JJ, Collins AJ. Association of Preventive Health Care with Atherosclerotic Heart Disease and Mortality in CKD. J Am Soc Nephrol. 2009 July; 20(7): 1614–1622.

2. Alves TP, Lewis J. Racial differences in chronic kidney disease (CKD) and end-stage renal disease (ESRD) in the United States: a social and economic dilemma. Clinical Nephrology. 2010;74(1):S72-S77.

3. Choi AI, Rodriguez RA, Bacchetti P, Bertenthal D, et al. White/Black Racial Differences in Risk of End-Stage Renal Disease and Death. Am J Med. 2009 July;122(7):672-678.

4. 1. US Renal Data System, USRDS 2010 Annual Data Report: Atlas of Chronic Kidney Disease and End-Stage Renal Disease in the United States, National Institutes of Health, National Institute of Diabetes and Digestive and Kidney Diseases, Bethesda, MD, 2010.

5. McClellan WM, Hodgin E, Pastan S, McAdams L, Soucie M. A Randomized Evaluation of Two Health Care Quality Improvement Program (HCQIP) Interventions to Improve the Adequacy of Hemodialysis Care of ESRD Patients: Feedback Alone versus Intensive Intervention. J Am Soc Nephrol 15:754-760, 2004

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:
Adequate dialysis dose (Kt/V > or = 1.2), is strongly associated with better outcomes, including decreased mortality, fewer hospitalizations, decreased length of hospitalizations, and decreased hospital costs.(1,2)

1. Plantinga LC, Fink NE, Jaar BG, et al. Attainment of clinical performance targets and improvement in clinical outcomes and resource use in hemodialysis care: a prospective cohort study. BMC Health Serv Res. 2007 Jan 9;7:5. http://www.ncbi.nlm.nih.gov/pmc/articles/PMC1783649/pdf/1472-6963-7-5.pdf. Accessed April 27, 2011.

2. Sehgal AR, Dor A, Tsai AC: Morbidity and cost implications of inadequate hemodialysis. Am J Kidney Dis 37:1223-1231, 2001

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.*]
Data show that the quality of some aspects of dialysis care has remained high. The percentage of patients receiving adequate hemodialysis with a mean delivered spKt/V = 1.2 increased from 85% in 1998 to 94% in 2008. In 2007, 95% of female patients and 89% of male patients received adequate hemodialysis.(1)

This measure was used in the CMS Physician Quality Reporting Initiative (PQRI), in the 2008 claims option and the 2009 and 2010 Registry option. The measure is also being used in the CMS Physician Quality Reporting System for 2011.(2)

There is a gap in care as shown by this 2008 data; 41.36 % of patients reported on did not receive the optimal care.
10th percentile: 7.80%
25th percentile: 29.77 %
50th percentile: 60.00 %
75th percentile: 79.29 %
90th percentile: 91.30%

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*]
1. 2008 Annual Report, End Stage Renal Disease Clinical Performance Measures Project. Department of Health and Human Services, Centers for Medicare & Medicaid Services, Office of Clinical Standards & Quality, Baltimore, Maryland, December 2008.

2. Confidential CMS PQRI 2008 Performance Information by Measure (PQRI Measure #81). Jan-Sept TAP file.

1b.4 Summary of Data on Disparities by Population Group: [*For Maintenance –Descriptive statistics for performance results for this measure by population group*]
1. Racial differences in the quality of dialysis care have been observed. In 1994, data from the core indicator project conducted by the Center of Medical and Medicaid Services (CMS) showed that 60% of African Americans on dialysis received an "inadequate" dose of dialysis (as defined by process, not outcome measures). Although evidence suggests that this percentage has decreased over time, in 1997 African Americans still had a 20% chance of receiving inadequate dialysis.

2. The proportion of all patients with an adequate hemodialysis dose increased 2-fold from 43% in 1993 to 86% in 2000. In 1993, 46% of white patients and 36% of black patients received an adequate dose. Corresponding figures for 2000 were 87% and 84%, respectively. Thus, the gap between white and black patients decresed from 10% to 3%.   In 1993, 54% of female patients and 31% of male patients received an adequate hemodialysis dosee. Corresponding figures for 2000 were 91% and 82%, respectively. Thus, the gap between female and male patients decreased from 23% to 9%. In addition, the magnitude of gaps between whites and blacks and between women and men varied by refion. Eleven regions had race gaps of 4% or less. However, no region had similarly small sex gaps.

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*]

1. Powe NR. To have and have not: Health and health care disparities in
chronic kidney disease. Johns Hopkins University School of Medicine, Baltimore, Maryland, USA, Kidney International, Vol. 64 (2003), pp. 763–772

2. Sehgal AR. Impact of Quality Improvement Efforts on Race and Sex Disparities in Hemodialysis. JAMA, February 26, 2003-Vol 289, No. 8.

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☐   <u>If not a health outcome</u>, 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)*:
This measure captures the number of calendar months during which patients have a spKt/V > or= 1.2, which is a measurement of the adequacy of hemodialysis, an intermediate clinical outcome. Adequate dialysis dose is linked to improved health outcomes such as attaining highest quality and quantity of life after onset of illness, decreasing morbidity and mortality, and increasing treatment effectiveness.

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 guideline recommendation focuses on the same patient population as the measure, patients receiving hemodialysis three times per week. The guideline states that the minimally adequate dose of HD given to this patient population should be an spKt/v (excluding [Residual Kidney Function] RKF) of 1.2 per dialysis. Therefore, the measure is written to capture the calendar months during which patients have a spKt/v > or = 1.2, consistent with the guideline recommendations.

1c.5 Quantity of Studies in the Body of Evidence *(Total number of studies, not articles)*: A total of 2,526 citations were screened, of which 319 were review articles and 14 were added by [NKF] Work Group members. There were 223 articles (191 studies in adults and 32 in children) that were potentially relevant. These articles were retrieved for full review. Of these, 87 adult articles were accepted for full data extraction by the Work Group members. Eight articles in children were formally data extracted by a pediatric nephrologist on the [NKF] Work Group. Articles in adults were randomly assigned to individual [NKF] Work Group members for data extraction. Of these, 23 studies answered questions pertinent to topics chosen for systematic listing in Summary Tables [within the guideline].

National Kidney Foundation. 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.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 present adequacy guideline for a minimally adequate dose remains unchanged from the previous (2000) guidelines. In deciding whether this guideline needed to be changed, the committee considered 3 lines of evidence. The first was results of the primary analysis of the NIH HEMO Study, published in 2002. The committee also had access to as-treated results of the HEMO Study, which were published at the time the draft guidelines were released in November 2005.98 This report was judged to be of some importance because it identified a dose-targeting bias in the analysis of delivered therapy versus mortality in cross-sectional data sets, which potentially impacts on the weight of evidence derived from such data sets. The second was a series of articles suggesting that dosing of dialysis should not be based on URR or its derivative, Kt/V (which essentially is volume of blood cleared divided by the modeled urea volume, V), but on the volume of blood cleared (Kt) only. The third was a series of analyses of delivered dose (ie, [Urea Reduction Ratio] URR) versus mortality based on either the USRDS-Medicare data set or the Fresenius Medical Care subset of these data.

HEMO Clinical Study: Primary (Randomized) Results
Primary results of the HEMO Study, which randomized patients to a delivered eKt/V of 1.16 versus 1.53, equivalent to URR values of about 63% versus 75% or spKt/V values of about 1.3 versus 1.7, revealed little evidence to support increasing the dose of dialysis beyond the current (2000) KDOQI recommendations, respectively. The lack of benefit, without even a trend that was close to statistical significance, appeared not only in the primary outcome of mortality, but also in a variety of main secondary composite outcomes relating to various causes of hospitalization combined with mortality. Furthermore, analysis of minor secondary composite outcomes dealing with nutritional measures—including changes in weight and serum albumin levels,as well as QOL measures—also failed to support a beneficial effect of increasing the dose of dialysis. Of all trials evaluated, the HEMO Study was by far the largest, and its randomized design and measurement of hard outcomes were given an enormous weight in determining whether the 2000 KDOQI HD Adequacy Guidelines needed to be changed. The Work Group realized that the recently published European guidelines recommended substantially higher minimal doses of HD based on an eKt/V measure, corresponding to spKt/V minimum targets of about 1.4 to 1.5.12

HEMO Clinical Study: As-Treated Results
The HEMO dose-versus-mortality question also was assessed within each treatment arm, measuring the effects of actual delivered dose over time versus mortality. This study identified a dose-targeting bias and suggested that patients in a cross-sectional analysis receiving less dialysis are also at greater risk for death. This increased death risk was of a high magnitude and was incompatible with a biological effect of dose. Although conditions of the 2 HEMO Study arms were not representative of how dialysis is prescribed in the field, documentation of such a strong potential dose-targeting bias (which may be operative in cross-sectional studies, albeit to a lesser degree) convinced the Work Group members to place less weight on dose-versus-mortality relationships derived from observational studies despite the large numbers of patients included in such studies.

Studies Advocating Alternate Measures of Urea-Based Adequacy
These studies are discussed in more detail in CPG 2, Methods for Measuring and Expressing the HD Dose. Since the 2000 KDOQI HD Adequacy Guidelines were published, 1 group of investigators in particular, using data derived from Fresenius Medical Care North America patients in the United States, argued that dose of dialysis should not be factored by modeled V [volume]. The arguments against using [Urea Reduction Ratio] URR or its derivative Kt/V fall into 2 general categories: (1) doing so may result in relative underdialysis of women and small patients of both sexes, and (2) because modeled V is itself a predictor of mortality, use of dialysis dose factored by V may confound dialysis dose-versus-mortality relationships found in cross-sectional studies in complex and not always predictable ways. A secondary analysis of the intent-to-treat results of the HEMO Study suggested that the higher dose of dialysis may result in better survival in women, who also tended to be smaller than the men in that particular trial. The Work Group decided, based on suggestive evidence, that more dialysis (beyond 2000 KDOQI levels) may be better for women and, perhaps, smaller patients, but that the level of evidence did not reach a point at which the existing guideline should be changed. Hence, 2 CPRs were derived suggesting that more dialysis in women and/or in smaller patients might be beneficial. Despite the theoretical arguments, as well as attempts to address confounding effects of V in cross-sectional data sets, the committee believed that, at present, the data are not compelling enough to depart from the 2000 recommendation to follow small-molecule clearance using Kt/V.

Limitations:
The main limitation to recommending adequate dosing of dialysis in patients following a thrice-weekly schedule is the difficulty performing randomized studies, as well as multiple confounding issues related to analysis of dose-mortality relationships in

observational studies. In the Work Group´s opinion, data from the HEMO Study suggested that the dose-benefit relationship for values of spKt/V in the current clinical setting are relatively flat at greater than the recommended minimum value of 1.2 thrice weekly. Many patient subgroups and perhaps all patients might benefit from more dialysis, but it seems that benefits would be derived primarily from extending dialysis treatment time markedly or moving to a more frequent dialysis schedule, as opposed to simply increasing urea Kt/V.

National Kidney Foundation. 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.7 Consistency of Results across Studies *(Summarize the consistency of the magnitude and direction of the effect):* Since the KDOQI 2000 HD Adequacy guidelines were published, a number of studies, including analyses of USRDS Annual Data Reports, continued to examine the relationship between dose of dialysis and mortality. Most, but not all, observational studies reported dose in terms of either spKt/V or [Urea Reduction Ratio] URR. The dose-versus-mortality relationship was examined as a function of race and sex and as influenced by various measures of body size and nutritional status. Because the general median spKt/V increased over time, these analyses included much larger samples of patients receiving higher doses of dialysis. Most of these analyses suggested that increasing the dose of dialysis above the target recommended in the 2000 guidelines to levels targeted in the high-dose arm of the HEMO Study (spKt/V ~ 1.7) should decrease mortality by a substantial amount. However, the lack of concordance between these observational results and negative results of the HEMO Study, coupled with the dose-targeting bias identified in the as-treated analysis of HEMO Study patients, restrained the Work Group from recommending a global increase in recommended spKt/V for patients dialyzed 3 times per week.

National Kidney Foundation. 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.8 Net Benefit *(Provide estimates of effect for benefit/outcome; identify harms addressed and estimates of effect; and net benefit - benefit over harms)*:
The [NKF] Work Group focused more intently on the target dose and its relationship with the minimum dose which, in light of HEMO Study findings, remains 1.2 Kt/V units per dialysis for patients dialyzed 3 times per week. Data from the HEMO Study also revealed a coefficient of variation within patients of approximately 0.1 Kt/V units; therefore, the previous target of 1.3 was considered too low. To grant 95% confidence that the dose will not decrease to less than 1.2 per dialysis, the target dose was increased to 1.4 per dialysis. This is in keeping with current practice and is consistent with the target spKt/V of approximately 1.4 set by the European Standards Group.12 The Work Group favored high-flux membranes. The HEMO Study did not provide definitive answers, but data suggested that dialysis vintage and flux are related and CVD might be affected favorably by the use of high-flux dialysis. The issue of sex also was addressed by the [NKF] Work Group, which believed that dialysis doses and targets should remain the same in women compared with men. However, in light of suggestive findings from the HEMO Study and observational studies, clinicians should be aware of a possible increased responsiveness to dialysis in females compared with males.

Concern was raised by the Work Group about malnourished patients with respect to both the initiation and adequacy of HD. Initiation is confounded by errors in calculation of glomerular filtration rate (GFR) for patients with diminishing muscle mass, and adequacy is confounded by the effect of malnutrition on patients´ water volume (V), the denominator of the integrated urea clearance expression (Kt/V). Estimation equations for calculating GFR before starting dialysis therapy are based on serum creatinine level, but are adjusted for sex, size, race, and other factors that tend to alter the relationship between concentration and clearance. Most of these factors either increase or decrease the generation of creatinine, but the patient´s state of nutrition—which is well known to affect creatinine generation—is not a variable in this equation. The consequent error in malnourished patients would tend to underestimate GFR and thus endanger the patient from the ill consequences of the delayed initiation of dialysis therapy. In addition, if the patient is malnourished, dialysis probably is better started early.

After a patient starts dialysis therapy, loss of weight because of malnutrition will decrease V, increasing the Kt/V, potentially to values higher than the desired target range. Reducing the dialysis dose (Kt/V) in such patients may lead to potential harm from inadequate dialysis. The Work Group addressed this problem in Clinical Practice Recommendation (CPR) 4.6, which calls for an increase in Kt/V when signs of malnutrition are present. The magnitude of the increase is left to the clinician, who might take into consideration the absolute level of Kt/V and cause of the malnutrition. If Kt/V is already much greater than the minimum, an additional increase probably would not benefit the patient. Similarly, if malnutrition is caused by a condition other than uremia, increasing the dose may have no effect. This issue will require revisiting in the future, hopefully with more available hard data.

National Kidney Foundation. 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.9 Grading of Strength/Quality of the Body of Evidence. Has the body of evidence been graded? No

1c.10 If body of evidence graded, identify the entity that graded the evidence including balance of representation and any disclosures regarding bias: N/A

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

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

1c.13 Grade Assigned to the Body of Evidence: N/A

1c.14 Summary of Controversy/Contradictory Evidence: Given the increased use of conductivity to measure clearance during the dialysis session, the Work Group also considered using an anthropometric volume as the clearance denominator when clearance was measured by conductivity. Using an anthropometric volume as denominator was speculated to result in a more stable denominator, less affected by errors in predialysis and postdialysis urea nitrogen determinations. For example, $(Kecn \times T/Vant$, where Vant = anthropometrically-estimated total body water distribution volume) could be used instead of Kt/V urea. The Work Group´s conclusion was that there were not sufficient data comparing sequential dialysis adequacy measures by using both conductivity and urea kinetics in the same patients to make such a major revision, although it was recognized that from a quality-assurance perspective, it would be less challenging to ensure a constant dialysis dose given a more constant denominator. Concerns also were raised about altered modeled to anthropometric urea volume ratios in individual patients, although given the relative flatness of the adequacy to mortality curve, this issue may be of secondary importance.

Another potential strategy discussed was to normalize the dialysis amount to a denominator based on BSA as opposed to urea volume, whether the latter was derived from modeling or anthropometrics. For example, this is accomplished easily by multiplying the target Kt/V value by $3.27 \times V/V0.667$ (V raised to the 2/3 power). Such a correction method (developed by the Frequent HD Network investigators) gives the same dialysis dose when V = 35 L, but then augments the dose when V is less than this amount and reduces the dose when V is larger, giving, in effect, a dose based on BSA instead of V. Again, for lack of definitive clinical outcomes evidence supporting this approach, it was left for perhaps a future revision of the guidelines when more data might be available.

National Kidney Foundation. 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.15 Citations for Evidence other than Guidelines*(Guidelines addressed below)***:**
N/A

1c.16 Quote verbatim, <u>the specific guideline recommendation</u> *(Including guideline # and/or page #)*:
The minimally adequate dose of HD given 3 times per week to patients with Kr less than 2 mL/min/1.73m2 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 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: NKF Hemodialysis Adequacy Work Group Membership: John T. Daugirdas, MD (Co-Chair), is a Clinical Professor of Medicine at the University of Illinois College of Medicine. His areas of interest include dialysis adequacy and dialysis hypotension. He is a member of the American Society of Nephrology and the International Society of Nephrology and a founding member of the International Society of Hemodialysis. He was the Principal Investigator of one of the 15 Clinical Centers participating in the HEMO Study and currently is a Consultant to the Data Coordinating Center for the Frequent Hemodialysis Network trial of short-daily and nocturnal hemodialysis. Dr Daugirdas is one of the editors of the Handbook of Dialysis and is founding editor of the electronic journal, Hypertension, Dialysis, and Clinical Nephrology. He has received grants from Watson, American Regent, Aksys, Nephros, RRI, HDC Medical, Advanced Renal Technologies, Amgen, Ortho Biotech, Shire, Roche, Astra Zeneca, and Neurochem. Thomas A. Depner, MD (Co-Chair), is a Professor of Medicine in the Department of Internal Medicine, Division of Nephrology, at the University of California, Davis School of Medicine. He trained at the University of Portland in Oregon, at Johns Hopkins University Medical School in Baltimore, and at Case Western Reserve University, where he completed his residency in internal medicine at University Hospitals in Cleveland. He is a practicing board-certified nephrologist with a long-standing interest in hemodialysis. He currently is the director of dialysis services at the University of California, Davis, and has authored a textbook on the prescription of hemodialysis. He is a member of the American Society of Nephrology, the International Society of Nephrology, the American Society for Artificial Internal Organs, and a founding member of the International Society of Hemodialysis. He was involved as a Principal Investigator during the HEMO Study and similarly is involved in the NIH-Clinical Trial: Frequent Hemodialysis Network clinical trial. He has been a member of the board of trustees for the American Society for Artificial Internal Organs since 1997 and is a past president of that organization. He has served on the dialysis advisory council for the American Society of Nephrology and on the editorial board of NephSAP. Stuart Goldstein, MD, is an Associate Professor of Pediatrics at the Baylor College of Medicine in Houston, TX. He is Medical Director of the Dialysis Unit at the Texas Children´s Hospital and Administrative Director of the Pheresis Service at the Texas Children´s Hospital, both of Houston. He is a member of the American Academy of Pediatrics, the American Society of Nephrology, the International Pediatric Nephrology Association, the American Society of Pediatric Nephrology, the International Society of Nephrology, and the Society for Pediatric Research. In addition, he is on the Medical Review Board for the End-Stage Renal Disease Network of Texas, the Pediatric Nephrologist Representative for the International Society of Nephrology Commission of Acute Renal Failure, on the Clinical Affairs Committee for the American Society of Pediatric Nephrology, on the Dialysis Advisory Group for the American Society of Nephrology, and on the Training/Certification Committee of the American Society of Pediatric Nephrology. He has received grants from Gambro Renal Products, Dialysis Solutions Inc, Baxter Healthcare, B. Braun Inc, Amgen Inc, Abbott Laboratories, and Toray Inc. He has also lectured for Genentech. Dr Goldstein has received research funds, grants, or contracts from American Academy of Pediatrics, Baxter Healthcare, Dialysis Solutions, Inc., Gambro Renal Products, Genentech, Luitpold Pharmaceuticals, NxStage Inc., and The University of Missouri. Todd S. Ing, MD, joined the Hines Veterans Affairs Hospital as a nephrologist and the Loyola University Chicago Stritch School of Medicine as a faculty member in 1976, after a number of years in private practice. Committed to medical education, he is an editor of the Handbook of Dialysis. Topics of special interest to him include the formulation of dialysates, bicarbonate-buffered peritoneal dialysis, first-use syndrome, peritoneal sclerosis, peritoneal fluid eosinophilia, dialysis ascites, and dialysis-associated pericarditis. Dr Ing has received research funds, grants, or contracts from Abbott Laboratories and Aksys Ltd. Victoria Kumar, MD, is Associate Professor of Medicine, Department of Internal Medicine, Division of Nephrology, University of California Davis Medical Center. Dr Kumar´s fellowship was at University of California Davis Medical Center. Dr Kumar also is staff physician at the Kaiser Permanente Medical Group. Klemens B. Meyer, MD, is Associate Professor of Medicine at Tufts University School of Medicine. He serves as Director of Dialysis Services, Chair of the Health Information Committee, and Division of Nephrology Webmaster at Tufts-New England Medical Center. He founded Dialysis Clinic Inc´s (DCI´s) Outcomes Monitoring Program and serves as DCI´s Medical Director for Information Technology. He has chaired both the Medical Review Board and the Board of Directors for End-Stage Renal Disease Network 1. He participated in the design and execution of the HEMO and CHOICE Studies. He is an active participant in the NKF KEEP programs and other regional chronic kidney disease screening and education programs. Dr Meyer´s particular interests include informatics and decision support in chronic kidney disease stages IV and V and clinical applications of measures of patient experience. Dr Meyers has received research funds, grants, or contracts from Primary Insight Contributor Network, MEDA Corp/Leerink Swann & Co., and Gerson Lehram Healthcare Council. Keith Norris, MD, is board certified in internal medicine and nephrology and is a certified hypertension specialist. He is the director of the Clinical Research Center at the Charles R. Drew University of Medicine and Science in Los Angeles, CA, where he also serves as the Vice-President of Research. He serves as a continuing quality improvement and quality assurance advisor to industry and has published more than 100 articles and book chapters. He is the principal investigator for a National Institutes of Health comprehensive center for health disparities in chronic kidney disease. Dr Norris has received research funds, grants, or contracts from Abbott Laboratories, Amgen, Genzyme/Bone Care International, Merck, and Pfizer. Evidence Review Team: National Kidney Foundation Center for Guideline Development and Implementation at Tufts-New England Medical Center, Boston, MA Ethan Balk, MD, MPH, Project Director, Hemodialysis and Peritoneal Dialysis Adequacy George Fares, MD, Assistant Project Director, Hemodialysis and Peritoneal

Dialysis Adequacy Ashish Mahajan, MD, MPH, Assistant Project Director, Vascular Access, Hemodialysis and Peritoneal Dialysis Adequacy Amy Earley, BS Rebecca Persson, BA Gowri Raman, MD Christina Kwack Yuhan, MD Priscilla Chew, MPH Stanley Ip, MD Mei Chung, MPH

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

1c.22 If other, identify and describe the grading scale with definitions: The strength of each guideline recommendation is based on the quality of the supporting evidence as well as additional considerations. Additional considerations, such as cost, feasibility, and incremental benefit were implicitly considered.

A   It is strongly recommended that clinicians routinely follow the guideline for eligible patients. There is strong evidence that the practice improves health outcomes.
B   It is recommended that clinicians routinely follow the guideline for eligible patients. There is moderately strong evidence that the practice improves health outcomes.
CPR   It is recommended that clinicians consider following the guideline for eligible patients. This recommendation is based on either weak evidence or on the opinions of the Work Group and reviewers that the practice might improve health outcomes.

Health outcomes are health-related events, conditions, or symptoms that can be perceived by individuals to have an important effect on their lives. Improving health outcomes implies that benefits outweigh any adverse effects.

1c.23 Grade Assigned to the Recommendation: A

1c.24 Rationale for Using this Guideline Over Others: It is the PCPI policy to use guidelines, which are evidence-based, applicable to physicians and other health-care providers, and developed by a national specialty organization or government agency. In addition, the PCPI has now expanded what is acceptable as the evidence base for measures to include documented quality improvement (QI) initiatives or implementation projects that have demonstrated improvement in quality of care.

KDOQI was founded on the principles of structured review of the literature, with data abstraction of pertinent articles. All of the KDOQI guidelines were developed in this manner. Since the first guideline was published, additional refinement and maturation of this process has occurred. This rigorous process of guideline development has been well received as both credible and transparent. National Kidney Foundation. KDOQI Guideline Processed. http://www.kidney.org/professionals/KDOQI/guidelines_process.cfm. Accessed: May 19, 2011.

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:** Moderate

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: www.physicianconsortium.org

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)*:
Calendar months during which patients have a spKt/V > or = 1.2

Note: Urea kinetic modeling (UKM) or the second generation Daugirdas formula (simplified multivariable equation) are the most appropriate ways to calculate spKt/V, and the two accepted methods for calculating spKt/V per the KDOQI guidelines. For more information on these methods, please refer to National Kidney Foundation's 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).

2a1.2 Numerator Time Window *(The time period in which the target process, condition, event, or outcome is eligible for inclusion)*:
Each calendar month within measurement 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)*:
See attached for EHR specifications.

For Claims/Administrative:
Report CPT II code 3XXXF: spKt/V greater than or equal to 1.2 (single-pool clearance of urea [Kt]/volume[V])

2a1.4 Denominator Statement *(Brief, narrative description of the target population being measured)*:
All calendar months during which patients aged 18 years and older with a diagnosis of ESRD are receiving hemodialysis three times a week

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)*:
12 consecutive calendar months

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)*:
See attached for EHR specifications.

For Claims/Administrative: See coding tables attached for coding (ICD-9-CM, ICD-10-CM, CPT)

2a1.8 Denominator Exclusions *(Brief narrative description of exclusions from the target population)*:
Documentation of medical reason(s) for patient not having a spKt/V > or = 1.2 (eg, patient has residual kidney function, other medical reasons)

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)*:
Append modifier to CPT II code 3XXXF-1P

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)*:
We encourage the results of this measure to be stratified by race, ethnicity, gender, and primary language, and have included these variables as recommended data elements to be collected.

2a1.11 Risk Adjustment Type *(Select type. Provide specifications for risk stratification in 2a1.10 and for statistical model in 2a1.13)*: Other   **2a1.12 If "Other," please describe:** We account for risk adjustment by inclusion of the exceptions for this measure.

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.)*:
Exceptions for this measure are listed above, in section 2a1.8.

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.)*:
Calculation algorithm is included in data dictionary/code table attachment (2a1.30).

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

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):
This measure does not require sampling or a survey.

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

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.*): N/A

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

2a1.30-32 Data Dictionary/Code Table Web Page URL or Attachment:
Attachment
AMA-PCPI_AKID-10_HDAdequacy_11.8.2011.pdf

2a1.33 Level of Analysis (*Check the levels of analysis for which the measure is specified and tested)*: Clinician : Group/Practice, Clinician : Individual, Clinician : Team

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2a1.34-35 Care Setting *(Check all the settings for which the measure is specified and tested)*: Ambulatory Care : Clinician Office, Dialysis Facility, Home Health, Post Acute/Long Term Care Facility : Nursing Home/Skilled Nursing 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)*:
PCPI Testing Project:
•	Four nephrology practice sites representing various types, locations and sizes were identified to participate in testing the measures
o	The number of physicians per site ranged from 5-62 physicians
o	The sites were located in four different regions: Midwestern, Western, Eastern, and Southern
o	Patient visit volume ranged from 240-2,800 ESRD patients seen per month
•	Sample size per physician organization ranged from 24-30 (as shown below) for a total of 169 ESRD patients on Peritoneal Dialysis (PD), or Hemodialysis (HD)
o	Site 1: 27 ESRD patients (3 PD patients, 24 HD patients)
o	Site 2 :40 ESRD patients (10 PD patients, 30 HD patients)
o	Site 3 :42 ESRD patients (19 PD patients, 23 HD patients)
o	Site 4 : 60 ESRD patients (30 PD patients, 30 HD patients)
•	Sample selection: Data were collected from the medical records of the first up to 35 ESRD patients on each type of dialysis seen at each site after July 1, 2007.
•	Data abstraction was completed for multiple patient visits per patient for a total of 1109 patient visits.
•	Data abstraction was performed in 2008

2a2.2 Analytic Method *(Describe method of reliability testing & rationale)*:
Data abstracted from patient records were used to calculate inter-rater reliability for the measure.
Patients were randomly selected from visits for ESRD.
Data analysis included:
•	Percent agreement
•	Kappa statistic with 95% confidence interval to adjust for chance agreement

2a2.3 Testing Results *(Reliability statistics, assessment of adequacy in the context of norms for the test conducted)*:
N, % Agreement, Kappa (95% Confidence Interval)
Kt/V=1.2: 756, 99.74%, 0.00 (-1.38,1.38)
Kt/V<1.2 with documented POC: 1, 100%, 1.00 (n/a)
Kt<1.2 without documented POC: 29,100%, 1.00† (n/a)

*This is an example of a limitation of the Kappa statistic. The "kappa is significantly reduced if one classification category dominates" (http://www.ajronline.org/cgi/content/full/184/5/1391).

†Kappa statistics cannot be calculated but are given a value of 1.00 because of complete agreement. Confidence intervals cannot be calculated because to do so would involve dividing by zero which cannot be done.

2b. VALIDITY. Validity, Testing, <u>including all Threats to Validity</u>:   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 guideline recommendation focuses on the same patient population as the measure, patients receiving hemodialysis three times per week. The guideline states that the minimally adequate dose of HD given to this patient population should be an spKt/v (excluding [Residual Kidney Function] RKF) of 1.2 per dialysis. Therefore, the measure is written to capture the calendar months during which patients have a spKt/v > or = 1.2, consistent with the guideline recommendations.

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)*:

An expert panel was used to assess face validity of the measure. This panel consisted of 21 members, with representation from the following specialties: nephrology, pediatric nephrology, endocrinology, nursing, methodology, internal medicine, preventive medicine and family medicine.

Louis H. Diamond, MBChB, FCP (SA), FACP, FHIMSS (Work Group Co-Chair) (Nephrology, Methodology) President, Quality Healthcare Consultants, Rockville, MD
Barbara Fivush, MD (Work Group Co-Chair) (Nephrology - Pediatrics) Professor of Pediatrics, Division Chief of Pediatric Nephrology, Johns Hopkins University, Baltimore, MD
Paul M. Palevsky, MD, FACP, FCCD, FASN (Work Group Co-Chair) (Nephrology - Adult) Professor of Medicine, University of Pittsburgh School of Medicine, Chief, Renal Section, VA Pittsburgh Healthcare System, Pittsburgh, PA
Eileen D. Brewer, MD (Nephrology - Pediatrics) Professor and Head, Pediatric Renal Section, Baylor College of Medicine Chief, Renal Service, Texas Children´s Hospital, Houston, TX
John W. Foreman, MD (Nephrology - Pediatrics) Department of Pediatrics, Professor of Pediatrics, Duke University, Durham, NC
Richard S. Goldman, MD (Nephrology - Adult, Methodology) Nephrology and Internal Medicine, Albuquerque, NM
Stuart L. Goldstein, MD (Nephrology - Pediatrics) Director, Center for Acute Care Nephrology, Cincinnati Children's Hospital Medical Center; Medical Director, Pheresis Service, Professor of Pediatrics, University of Cincinnati College of Medicine, Cincinnati, OH
John Hartman, MD (Nephrology - Adult) CEO, Visonex, LLC, Treasurer, Wisconsin Medical Society, Green Bay, WI
Richard Hellman, MD, FACP, FACE (Endocrinology, Methodology) Clinical Professor of Medicine, University of Missouri-Kansas City School of Medicine, Private Practice, Diabetes & Endocrinology, North Kansas City, MO
Jean L. Holley, MD, FACP (Nephrology - Adult) Clinical Professor of Medicine, University of Illinois, Urban-Champaign and Carle Physician Group, Urbana, IL
Edward R. Jones, MD (Nephrology - Adult) Self-Employed, Delaware Valley Nephrology Associates, Philadelphia, PA
Karen M. Kolbusz, RN, BSN, MBA, (Nursing, Joint Commission Liaison) Associate Project Director, The Joint Commission, Oakbrook Terrace, IL
Craig B. Langman, MD (Nephrology - Pediatrics) The Isaac A. Abt MD Professor of Kidney Diseases and Head, Kidney Diseases, Feinberg School of Medicine, Northwestern University, and Children´s Memorial Hospital, Chicago, IL
Rajnish Mehrotra, MD (Nephrology - Adult) Professor of Medicine at David Geffen School of Medicine at UCLA and Associate Chief, Div of Nephrology and Hypertension, Harbor-UCLA Medical Center, Torrance, CA
Alvin H. Moss, MD (Nephrology - Adult) Professor of Medicine, West Virginia University, Morgantown, WV
Sharon A. Perlman, MD (Nephrology - Pediatrics) USF Pediatric Nephrology, All Children´s Hospital, St. Petersburg, FL
Paul D. Rockswold, MD, MPH (Preventive Medicine and Family Medicine) Physician Epidemiologist, Head of Health Analysis, Navy and Marine Corps Public Health Center, Suffolk, VA
Candace C. Walworth, MD (Nephrology - Adult) Nephrology and Internal Medicine, Lewiston, ME
Bradley Warady, MD (Nephrology - Pediatrics) Chief, Pediatric Nephrology, Children´s Mercy Hospitals and Clinics, Kansas City, MO
Steven J. Wassner, MD, FAAP (Nephrology - Pediatrics) Professor of Pediatrics, Vice-Chair for Education, Chief, Division of Nephrology & Hypertension, Hershey, PA
Jerry Yee, MD (Nephrology - Adult) Division Head, Nephrology and Hypertension, Henry Ford Hospital, Detroit, MI

2b2.2 Analytic Method *(Describe method of validity testing and rationale; if face validity, describe systematic assessment)*:
Face validity of the measure score as an indicator of quality was systematically assessed as follows:

After the measure was fully specified, the expert panel (workgroup membership) was asked to rate their agreement with the following statement:

Please rate your agreement with the following statement for each measure:

The scores obtained from the measure as specified will accurately differentiate quality across providers.

Scale 1-5, where 1=Strongly Disagree; 3=Neither Disagree nor Agree; 5=Strongly Agree

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)*:

The results of the expert panel rating of the validity statement were as follows: N = 19; Mean rating = 4.63
Frequency Distribution of Ratings
1 - 0 (Strongly Disagree)
2 - 0
3 - 0 (Moderate Agreement)
4 - 7
5 -12 (Strongly Agree)

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)*:
•   At the time of testing, this measure did not have exclusions.

2b3.2 Analytic Method (*Describe type of analysis and rationale for examining exclusions, including exclusion related to patient preference)*:
•   At the time of testing, this measure did not have exclusions.

2b3.3 Results *(Provide statistical results for analysis of exclusions, e.g., frequency, variability, sensitivity analyses):*
•   At the time of testing, this measure did not have exclusions.

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)*:
We account for risk adjustment by inclusion of the exceptions 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)*:
We account for risk adjustment by inclusion of the exceptions for this measure.

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)*:
We account for risk adjustment by inclusion of the exceptions for this measure. These exceptions are newly added and were not included in existing testing data.

2b4.4 If outcome or resource use measure is not risk adjusted, provide rationale and analyses to justify lack of adjustment: N/A

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)*:
PCPI Testing Project:
•   Four nephrology practice sites representing various types, locations and sizes were identified to participate in testing the measures
o   The number of physicians per site ranged from 5-62 physicians
o   The sites were located in four different regions: Midwestern, Western, Eastern, and Southern
o   Patient visit volume ranged from 240-2,800 ESRD patients seen per month
•   Sample size per physician organization ranged from 24-30 (as shown below) for a total of 169 ESRD patients on

Peritoneal Dialysis (PD), or Hemodialysis (HD)
o   Site 1: 27 ESRD patients (3 PD patients, 24 HD patients)
o   Site 2 :40 ESRD patients (10 PD patients, 30 HD patients)
o   Site 3 :42 ESRD patients (19 PD patients, 23 HD patients)
o   Site 4 : 60 ESRD patients (30 PD patients, 30 HD patients)
•   Sample selection: Data were collected from the medical records of the first up to 35 ESRD patients on each type of dialysis seen at each site after July 1, 2007.
•   Data abstraction was completed for multiple patient visits per patient for a total of 1109 patient visits.
•   Data abstraction was performed in 2008

CMS Physician Quality Reporting Initiative:
For the measure, Plan of Care for Inadequate Hemodialysis, 160,065 eligible patient visits were reported in the clinical performance denominator for the 2008 program - the most recent year for which data are available. The clinical performance denominator is the total number of eligible instances reported minus the number of eligible instances excluded from the measure.

2b5.2 Analytic Method *(Describe methods and rationale to identify statistically significant and practically/meaningfully differences in performance)*:
CMS Physician Quality Reporting Initiative
The inter-quartile range (IQR) was calculated. It provides a measure of the dispersion of performance for each measure.

ESRD CPM*
A national random sample of adults aged =18 years in-center hemodialysis patients stratified by Network, who were alive on December 31, 2006, was selected (n=8,937). 8,740 patients
(97.8%) were included in the sample for analysis.
•   87% of patients had monthly adequacy measurements performed
•   93% of patients on dialysis for 6 months or more and dialyzing 3 times per week had a mean delivered adequacy dose of spKt/V=1.12 calculated using the Daugirdas II formula

*The data is taken from the 2007 DHHS ESRD Clinical Performance Measures (CPM) Project.
http://www.cms.gov/CPMProject/Downloads/ESRDCPMYear2007Report.pdf

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)*:
 PCPI Testing Project Results:
Scores on this measure
N = 1282 Mean = 68 % Range = (42%-93%)
Kt=1.2: 756/1282 Mean = 59% Range = (42%-76%)

CMS Physician Quality Reporting Initiative:
This measure was used in the CMS Physician Quality Reporting Initiative (PQRI), in the 2008 claims option and the 2009 and 2010 Registry.

41.36% of patients reported on did not receive the optimal care. There is significant variation in performance on this measure in the PQRI program as shown by the 2008 data, the most recent available.*
10th percentile: 7.80%
25th percentile: 29.77 %
50th percentile: 60.00 %
75th percentile: 79.29 %
90th percentile: 91.30%

The inter-quartile range (IQR) provides a measure of the dispersion of performance. The IQR is 49.52%, and indicates that 50% of physicians have performance on this measure ranging from 29.77% and 79.29%. A quarter of reporting physicians have performance on this measure which is greater than 79.29%, while a quarter have performance on this measure less than 29.77%.

Data found in the Confidential CMS PQRI 2008 Performance Information by Measure (PQRI Measure #81). Jan-Sept TAP file.

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)*:
PCPI Testing Project:
•   Two nephrology practice sites representing various types, locations and sizes which participated in the CMS PQRI Project in 2007 were identified to participate in testing the measures
•   Sample size across the two physician offices as 202 patient visits
•   Sample selection: Data were collected from the medical records of the first up to 35 ESRD patients on each type of dialysis seen at each site after July 1, 2007.
•   Data abstraction was performed in 2008

2b6.2 Analytic Method (*Describe methods and rationale for testing comparability of scores produced by the different data sources specified in the measure)*:
Data abstracted from patient records were used to calculate parallel-forms reliability for the measure.
Patients were randomly selected from visits for ESRD
Data analysis included:
•   Percent agreement
•   Kappa statistic to adjust for chance agreement

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)*:
Plan of Care for Inadequate Hemodialysis (N, % Agreement)
202, 64.9% Agreement

It should be noted that there were instances where the wrong quality data code was inserted on the claim based, in the documented laboratory results available. This was likely due to the practice of some dialysis facilities to routinely bill on the first of every month. For example, this would cause a June bill to refer to laboratory results from May. This test was run in the first year of the program implementation which may have affected results as well.

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)*: We encourage the results of this measure to be stratified by race, eithnicity, gender, and primary language, and have included these variables as recommended data elements to be collected.

2c.2 If disparities have been reported/identified (e.g., in 1b), but measure is not specified to detect disparities, please explain:
The PCPI advocates that performance measure data should, where possible, be stratified by race, ethnicity, and primary language to assess disparities and initiate subsequent quality improvement activities addressing identified disparities, consistent with recent national efforts to standardize the collection of race and ethnicity data. A 2008 NQF report endorsed 45
practices including stratification by the aforementioned variables.(1) A 2009 IOM report "recommends collection of the existing Office of Management and Budget (OMB) race and Hispanic ethnicity categories as well as more fine-grained categories of ethnicity(referred to as granular ethnicity and based on one's ancestry) and language need (a rating of spoken English language proficiency of less than very well and one's preferred language for health-related encounters)."(2)

References:
(1)National Quality Forum Issue Brief (No.10). Closing the Disparities Gap in Healthcare Quality with Performance Measurement and Public Reporting. Washington, DC: NQF, August 2008.

(2)Race, Ethnicity, and Language Data: Standardization for Health Care Quality Improvement. March 2010. AHRQ Publication No. 10-0058-EF. Agency for Healthcare Research and Quality, Rockville, MD. Available at:

http://www.ahrq.gov/research/iomracereport. Accessed May 25, 2010.

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)*: Professional Certification or Recognition Program, Public Reporting, Quality Improvement (Internal to the specific organization)

3.1 **Current Use** *(Check all that apply; for any that are checked, provide the specific program information in the following questions)*: Public Reporting, Professional Certification or Recognition Program, 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.*]
This measure was used in the CMS Physician Quality Reporting Intitiative in 2008, 2009, and 2010. The results from the 2008-2010 PQRI programs can be found on the CMS website:

http://www.cms.gov/PQRS/01_Overview.asp#TopOfPage

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: The PCPI, RPA, and ASPN believe that the reporting of participation information is a beneficial first step on a trajectory toward the public reporting of performance results, which is appropriate since the measure has been tested and the reliability of the performance data has been validated. NQF endorsement will facilitate our ongoing progress toward this public reporting objective.

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 may be used in a Maintenance of Certification program.

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*].
All PCPI measures are suitable for use in quality improvement initiatives and are made freely available on the PCPI website and through the implementation efforts of medical specialty societies and other PCPI members. The PCPI strongly encourages the use of its measures in QI initiatives and seeks to provide information on such initiatives to PCPI members.

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

The PCPI, RPA and ASPN believe that the use of PCPI measures in quality improvement initiatives is a beneficial way to gather scientific data with which to improve physician performance. This is appropriate since the measure has been tested and the reliability of the performance data has been validated. NQF endorsement will facilitate our ongoing progress toward this quality improvement objective.

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:
We are not aware of any unintended consequences related to this measurement.

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)*:
This measure was found through testing to be both feasible and reliable. Data collection was performed in a reasonable timeframe. There is no fee for use of the measure.

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): American Medical Association - Physician Consortium for Performance Improvement, 515 N. State St., Chicago, Illinois, 60654

Co.2 Point of Contact: Mark S., Antman, DDS, MBA, Director, Measure Development Operations Performance Improvement, mark.antman@ama-assn.org, 312-464-5056-

Co.3 Measure Developer if different from Measure Steward: American Medical Association - Physician Consortium for Performance Improvement, 515 N. State St., Chicago, Illinois, 60654

Co.4 Point of Contact: Katherine, Ast, MSW, LCSW, katherine.ast@ama-assn.org, 312-464-4920-

Co.5 Submitter: Diedra, Joseph, MPH, diedra.joseph@ama-assn.org, 312-464-4904-, American Medical Association - Physician Consortium for Performance Improvement

Co.6 Additional organizations that sponsored/participated in measure development:
Renal Physicians Association, American Society of Pediatric Nephrology

Co.7 Public Contact: Mark, Antman, DDS, MBA, mark.antman@ama-assn.org, 312-464-5056-, American Medical Association - Physician Consortium for Performance Improvement

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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.
Louis H. Diamond, MBChB, FCP (SA), FACP, FHIMSS (Work Group Co-Chair) (Nephrology, Methodology) President, Quality Healthcare Consultants, Rockville, MD
Barbara Fivush, MD (Work Group Co-Chair) (Nephrology - Pediatrics) Professor of Pediatrics, Division Chief of Pediatric Nephrology, Johns Hopkins University, Baltimore, MD
Paul M. Palevsky, MD, FACP, FCCD, FASN (Work Group Co-Chair) (Nephrology - Adult) Professor of Medicine, University of Pittsburgh School of Medicine, Chief, Renal Section, VA Pittsburgh Healthcare System, Pittsburgh, PA

Eileen D. Brewer, MD (Nephrology - Pediatrics) Professor and Head, Pediatric Renal Section, Baylor College of Medicine Chief, Renal Service, Texas Children´s Hospital, Houston, TX
John W. Foreman, MD (Nephrology - Pediatrics) Department of Pediatrics, Professor of Pediatrics, Duke University, Durham, NC
Richard S. Goldman, MD (Nephrology - Adult, Methodology) Nephrology and Internal Medicine, Albuquerque, NM
Stuart L. Goldstein, MD (Nephrology - Pediatrics) Director, Center for Acute Care Nephrology, Cincinnati Children's Hospital Medical Center; Medical Director, Pheresis Service, Professor of Pediatrics, University of Cincinnati College of Medicine, Cincinnati, OH
John Hartman, MD (Nephrology - Adult) CEO, Visonex, LLC, Treasurer, Wisconsin Medical Society, Green Bay, WI
Richard Hellman, MD, FACP, FACE (Endocrinology, Methodology) Clinical Professor of Medicine, University of Missouri-Kansas City School of Medicine, Private Practice, Diabetes & Endocrinology, North Kansas City, MO
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Edward R. Jones, MD (Nephrology - Adult) Self-Employed, Delaware Valley Nephrology Associates, Philadelphia, PA
Karen M. Kolbusz, RN, BSN, MBA, (Nursing, Joint Commission Liaison) Associate Project Director, The Joint Commission, Oakbrook Terrace, IL
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Steven J. Wassner, MD, FAAP (Nephrology - Pediatrics) Professor of Pediatrics, Vice-Chair for Education, Chief, Division of Nephrology & Hypertension, Hershey, PA
Jerry Yee, MD (Nephrology - Adult) Division Head, Nephrology and Hypertension, Henry Ford Hospital, Detroit, MI

PCPI measures are developed through cross-specialty, multi-disciplinary work groups. All medical specialties and other health care professional disciplines participating in patient care for the clinical condition or topic under study are invited to participate as equal contributors to the measure development process. In addition, the PCPI strives to include on its work groups individuals representing the perspectives of patients, consumers, private health plans, and employers. This broad-based approach to measure development ensures buy-in on the measures from all stakeholders and minimizes bias toward any individual specialty or stakeholder group. All work groups have at least two co-chairs who have relevant clinical and/or measure development expertise and who are responsible for ensuring that consensus is achieved and that all perspectives are voiced.

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: NQF# 0323, Hemodialysis Adequacy/Plan of Care
Steward: American Medical Association - Physician Consortium for Performance Improvement

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: 06, 2011
Ad.5 What is your frequency for review/update of this measure? Every 3 years or as new evidence becomes available that materially affects the measures.
Ad.6 When is the next scheduled review/update for this measure?

Ad.7 Copyright statement: Physician Performance Measures (Measures) and related data specifications have been developed by the American Medical Association (AMA) convened Physician Consortium for Performance Improvement® (PCPI™).

Ad.8 Disclaimers:

Ad.9 Additional Information/Comments: The next scheduled review/update for this measure will be in 2014.

The following updates were made on 11/09/11:

Specifications:
2a1.1 Numerator note was added regarding calculation methods
2a1.2 Time window was updated
2a1.6 Time window was updated

Importance:
1b.4 New disparities data added
1b.5 Citation for new disparities data added

Date of Submission (*MM/DD/YY*): 10/05/2011

PCPI eSpecification

Clinical Topic	Adult Kidney Disease
Measure Title	Hemodialysis Adequacy: Solute
Measure #	AKID-10
Measure Description	Percentage of calendar months within a 12-month period during which patients aged 18 years and older with a diagnosis of ESRD receiving hemodialysis three times a week have a spKt/V ≥ 1.2
Measurement Period	Twelve consecutive months
Initial Patient Population	Patient Age: Patient aged 18 years and older starts before the start of the measurement period Diagnosis Active: Patient has a diagnosis of ESRD starts before or during the measurement period Procedure Performed: Patient receiving hemodialysis exactly three times per week during the measurement period
Denominator Statement	All calendar months during which patients aged 18 years and older with a diagnosis of ESRD are receiving hemodialysis three times a week
Numerator Statement	Calendar months during which patients have a spKt/V ≥ 1.2
Denominator Exceptions	Documentation of medical reason(s) for patient not having a spKt/V ≥ 1.2 (eg, patient has residual kidney function, other medical reasons)

Adult Kidney Disease
DRAFT Data Elements for PCPI eSpecification

Measure 10--Hemodialysis Adequacy: Solute

QDM* Standard Category	QDM* Data Type	Standard Terminology	Constraints	Value Set Name	Value of Data Element	Data Source	Comments/Rationale
Measure Timing	N/A	N/A	TBD by measure implementer	Measurement Start Date			
Measure Timing	N/A	N/A	TBD by measure implementer	Measurement End Date			
Individual Characteristic	Patient Characteristic	TBD	during measurement period	Gender		• Electronic Administrative Claims • Electronic Health Record (EHR)	This data element is collected for the purpose of stratifying results in an effort to highlight disparities.
Individual Characteristic	Patient Characteristic	TBD	during measurement period	Race		• Electronic Health Record (EHR)	This data element is collected for the purpose of stratifying results in an effort to highlight disparities.
Individual Characteristic	Patient Characteristic	TBD	during measurement period	Ethnicity		• Electronic Health Record (EHR)	This data element is collected for the purpose of stratifying results in an effort to highlight disparities.
Individual Characteristic	Patient Characteristic	TBD	during measurement period	Primary Language		• Electronic Health Record (EHR)	This data element is collected for the purpose of stratifying results in an effort to highlight disparities.
Individual Characteristic	Patient Characteristic	LN	starts before the start of measurement period	Date of Birth		• Electronic Administrative Claims • Electronic Health Record (EHR)	
Individual Characteristic	Patient Characteristic	Calculated	starts before the start of measurement period	Age	≥ 18	• Electronic Administrative Claims • Electronic Health Record (EHR)	Measurement start date minus Date of Birth must be greater than or equal to 18 years.
Condition / Diagnosis / Problem	Diagnosis, Active	I9, I10, SNM	starts before or during measurement period	End Stage Renal Disease (ESRD)		• Electronic Administrative Claims • Electronic Health Record (EHR)	
Procedure	Procedure, Performed	CPT, SNM	during measurement period / 3x per week	Hemodialysis	count=3	• Electronic Administrative Claims • Electronic Health Record (EHR)	To be eligible for this measure, patient must be receiving hemodialysis exactly 3 times per week.
Encounter	Encounter, Performed	I9, I10	during measurement period / 3x per week	Hemodialysis - Encounter	count=3	• Electronic Administrative Claims • Electronic Health Record (EHR)	To be eligible for this measure, patient must be receiving hemodialysis exactly 3 times per week.
Laboratory Test	Laboratory Test, Performed	SNM	during each calendar month during measurement period	single-pool Kt/V		• Electronic Administrative Claims • Electronic Health Record (EHR)	
Laboratory Test	Laboratory Test, Result	SNM	most recent (last) during calendar month during measurement period	single-pool Kt/V	≥ 1.2	• Electronic Administrative Claims • Electronic Health Record (EHR)	
Negation Rationale	Laboratory Test, Not Done	SNM	during measurement period	Medical Reason(s)		• Electronic Health Record (EHR)	
Condition / Diagnosis / Problem	Diagnosis, Active	SNM	during measurement period	Residual Kidney Function		• Electronic Administrative Claims • Electronic Health Record (EHR)	

*The Quality Data Model (QDM), Version 2.1, was developed by National Quality Forum (NQF).
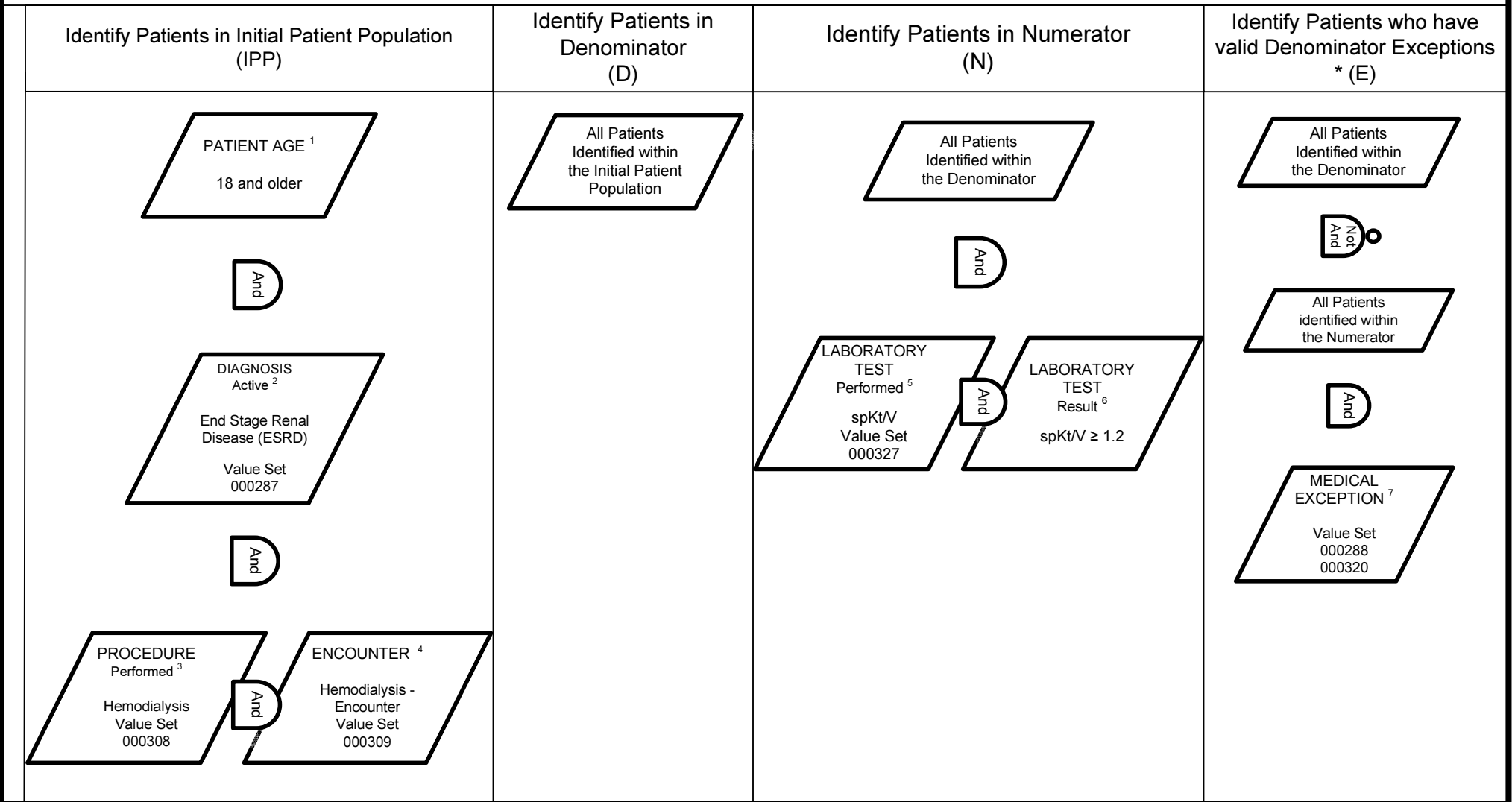
PCPI eSpecification

Measure Logic for Adult Kidney Disease : Hemodialysis Adequacy: Solute
Measure Description: Percentage of calendar months within a 12-month period during which patients aged 18 years and older with a diagnosis of ESRD receiving hemodialysis three times a week have a spKt/V ≥ 1.2
Period: 12 Consecutive Months
PCPI Measure #: AKID-10

Identify Patients in Initial Patient Population (IPP)	Identify Patients in Denominator (D)	Identify Patients in Numerator (N)	Identify Patients who have valid Denominator Exceptions * (E)

Identify Patients in Initial Patient Population (IPP)

PATIENT AGE [1]

18 and older

And

DIAGNOSIS
Active [2]

End Stage Renal Disease (ESRD)

Value Set
000287

And

PROCEDURE
Performed [3]

Hemodialysis
Value Set
000308

And

ENCOUNTER [4]

Hemodialysis - Encounter
Value Set
000309

Identify Patients in Denominator (D)

All Patients Identified within the Initial Patient Population

Identify Patients in Numerator (N)

All Patients Identified within the Denominator

And

LABORATORY TEST
Performed [5]

spKt/V
Value Set
000327

And

LABORATORY TEST
Result [6]

spKt/V ≥ 1.2

Identify Patients who have valid Denominator Exceptions * (E)

All Patients Identified within the Denominator

Not And

All Patients identified within the Numerator

And

MEDICAL EXCEPTION [7]

Value Set
000288
000320

PARAMETER SPECIFICATIONS (Value Sets are found in the Coding Appendices):
IPP: [1] Patient Age: measurement start date minus birth date (value set 000307) ≥ 18 years starts before the start of measurement period; [2] Diagnosis, Active: starts before or during measurement period; [3] Procedure, Performed: occurring exactly three times weekly during measurement period; [4] Encounter: occurring exactly three times weekly starts before or during measurement period;
N: [5] Laboratory Test, Performed: each month during measurement period; [6] Laboratory Test, Result: ≥ 1.2 each month during measurement period, if multiple results present during month use most recent (last) value;
E: All in (E) during measurement period;

*Coded examples are NOT intended to be an exhaustive list. Exceptions will vary for each patient and situation.

Basic Measure Calculation:

$$\frac{(N)}{(D) - (E)} = \%$$

The PCPI strongly recommends that exception rates also be computed and reported alongside performance rates as follows:

Exception Calculation:

$$\frac{(E)}{(D)} = \%$$

Exception Types:
E= E1 (Medical Exceptions) + E2 (Patient Exceptions) + E3 (System Exceptions)
For patients who have more than one valid exception, only one exception should be be counted when calculating the exception rate

Initial Patient Population (IPP)	Denominator (D)	Numerator (N)	Denominator Exceptions (E)
Definition: The initial patient population identifies the general group of patients that the performance measure is designed to address; usually focused on a specific clinical condition (e.g., coronary artery disease, asthma). For example, a patient aged 18 years and older with a diagnosis of CAD who has at least 2 Visits during the measurement period.	**Definition:** The denominator defines the specific group of patients for inclusion in a specific performance measure based on specific criteria (e.g., patient's age, diagnosis, prior MI). In some cases, the denominator may be I dentical to the initial patient population.	**Definition:** The numerator defines the group of patients in the denominator for whom a process or outcome of care occurs (e.g., flu vaccine received).	**Definition:** Denominator exceptions are the valid reasons why patients who are included in the denominator population did not receive a process or outcome of care (described in the numerator). Patients may have Denominator Exceptions for medical reasons (e.g., patient has an egg allergy so they did not receive flu vaccine); patient reasons (e.g., patient declined flu vaccine); or system reasons (e.g., patient did not receive flu Vaccine due to vaccine shortage). These cases are removed from the denominator population for the performance calculation, however the number of patients with valid exceptions should be calculated and reported. This group of patients constitutes the Denominator Exception reporting population – patients for whom the numerator was not achieved and a there is a valid Denominator Exception.
Find the patients who meet the Initial Patient Population criteria (IPP)	Find the patients who qualify for the denominator (D): ○ From the patients within the Patient Population criteria (IPP) select those people who meet Denominator selection criteria. (In some cases the IPP and D are identical).	Find the patients who qualify for the Numerator (N): ○ From the patients within the Denominator (D) criteria, select those people who meet Numerator selection criteria. ○ Validate that the number of patients in the numerator is less than or equal to the number of patients in the denominator	From the patients who did not meet the Numerator criteria, determine if the patient meets any criteria for the Denominator Exception (E1 + E2+E3). If they meet any criteria, they should be removed from the Denominator for performance calculation. As a point of reference, these cases are removed from the denominator population for the performance calculation, however the number of patients with valid exceptions should be calculated and reported.

ADULT KIDNEY DISEASE
Coding Spreadsheet for PCPI eSpecification
AKID-10 : Hemodialysis Adequacy : Solute

Value Set ID	Clinical Topic	Topic Indicator	Measure Component	Standard Concept	Standard Category	Taxonomy	Code	Code Descriptor
000307	AKID	10	IPP	Birth Date	Individual Characteristic	LN	21112-8	Birth date: TmStp:Pt:^Patient:Qn:
000287	AKID	10	IPP	End Stage Renal Disease (ESRD)	Diagnosis, Active	I9	585.6	End Stage Renal Disease [Chronic Kidney Disease, Stage V (requiring chronic dialysis)]
000287	AKID	10	IPP	End Stage Renal Disease (ESRD)	Diagnosis, Active	I10	N18.6	End Stage Renal Disease (chronic kidney disease requiring chronic dialysis)
000287	AKID	10	IPP	End Stage Renal Disease (ESRD)	Diagnosis, Active	SNM	46177005	end stage renal disease
000287	AKID	10	IPP	End Stage Renal Disease (ESRD)	Diagnosis, Active	SNM	236435004	end stage renal failure on dialysis
000308	AKID	10	IPP	Hemodialysis	Procedure	CPT	90957	
000308	AKID	10	IPP	Hemodialysis	Procedure	CPT	90958	
000308	AKID	10	IPP	Hemodialysis	Procedure	CPT	90959	
000308	AKID	10	IPP	Hemodialysis	Procedure	CPT	90960	
000308	AKID	10	IPP	Hemodialysis	Procedure	CPT	90961	
000308	AKID	10	IPP	Hemodialysis	Procedure	CPT	90962	
000308	AKID	10	IPP	Hemodialysis	Procedure	CPT	90965	
000308	AKID	10	IPP	Hemodialysis	Procedure	CPT	90966	
000308	AKID	10	IPP	Hemodialysis	Procedure	CPT	90969	
000308	AKID	10	IPP	Hemodialysis	Procedure	CPT	90970	
000308	AKID	10	IPP	Hemodialysis	Procedure	CPT	90989	
000308	AKID	10	IPP	Hemodialysis	Procedure	SNM	302497006	Hemodialysis
000308	AKID	10	IPP	Hemodialysis	Procedure	SNM	233578004	Continuous hemodialysis
000308	AKID	10	IPP	Hemodialysis	Procedure	SNM	233579007	Continuous arteriovenous hemodialysis
000308	AKID	10	IPP	Hemodialysis	Procedure	SNM	233580001	Continuous venovenous hemodialysis
000308	AKID	10	IPP	Hemodialysis	Procedure	SNM	427053002	Extracorporeal albumin hemodialysis
000308	AKID	10	IPP	Hemodialysis	Procedure	SNM	67970008	Hemodialysis, maintenance at home
000308	AKID	10	IPP	Hemodialysis	Procedure	SNM	68341005	Hemodialysis, supervision at home
000308	AKID	10	IPP	Hemodialysis	Procedure	SNM	57274006	Initial hemodialysis
000308	AKID	10	IPP	Hemodialysis	Procedure	SNM	233575001	Intermittent hemodialysis
000308	AKID	10	IPP	Hemodialysis	Procedure	SNM	233576000	Intermittent hemodialysis with sequential ultrafiltration
000308	AKID	10	IPP	Hemodialysis	Procedure	SNM	233577009	Intermittent hemodialysis with continuous ultrafiltration
000308	AKID	10	IPP	Hemodialysis	Procedure	SNM	11932001	Stabilizing hemodialysis
000308	AKID	10	IPP	Hemodialysis	Procedure	SNM	233589006	continuous arteriovenous hemodiafiltration
000308	AKID	10	IPP	Hemodialysis	Procedure	SNM	233590002	continuous venovenous hemodiafiltration
000327	AKID	10	N	spKt/V	Laboratory Test	SNM	440084005	assessment of adequacy of dialysis (procedure)
000327	AKID	10	N	spKt/V	Laboratory Test	SNM	375196010	kt/V
000327	AKID	10	N	spKt/V	Laboratory Test	SNM	375202013	kt/V - iteration
000327	AKID	10	N	spKt/V	Laboratory Test	SNM	375203015	kt/V - log ratio
000327	AKID	10	N	spKt/V	Laboratory Test	SNM	10189941000046106	Single pool kt/V
000288	AKID	10	E	Medical Exception	Negation Rationale	SNM	501000124106	Exclusion from performance measure for medical reason (finding)
000320	AKID	10	E	Residual Kidney Function	Diagnosis	SNM	411000124108	Hemodialysis residual renal function (observable entity)
000320	AKID	10	E	Residual Kidney Function	Diagnosis	SNM	10189931000046102	Residual renal function