NATIONAL QUALITY FORUM

Measure Evaluation 4.1
December 2009

This form contains the measure information submitted by stewards. Blank fields indicate no information was provided. Attachments also may have been submitted and are provided to reviewers. The subcriteria and most of the footnotes from the evaluation criteria are provided in Word comments within the form and will appear if your cursor is over the highlighted area. Hyperlinks to the evaluation criteria and ratings are provided in each section.

TAP/Workgroup (if utilized)**:** Complete all yellow highlighted areas of the form. Evaluate the extent to which each subcriterion is met. Based on your evaluation, summarize the strengths and weaknesses in each section.

Note: *If there is no TAP or workgroup, the SC also evaluates the subcriteria (yellow highlighted areas).*

Steering Committee: Complete all pink highlighted areas of the form. Review the workgroup/TAP assessment of the subcriteria, noting any areas of disagreement; then evaluate the extent to which each major criterion is met; and finally, indicate your recommendation for the endorsement. Provide the rationale for your ratings.

Evaluation ratings of the extent to which the criteria are met
C = Completely (unquestionably demonstrated to meet the criterion)
P = Partially (demonstrated to partially meet the criterion)
M = Minimally (addressed BUT demonstrated to only minimally meet the criterion)
N = Not at all (NOT addressed; OR incorrectly addressed; OR demonstrated to NOT meet the criterion)
NA = Not applicable (only an option for a few subcriteria as indicated)

(for NQF staff use) **NQF Review #:** 1421 **NQF Project:** End Stage Renal Disease

MEASURE DESCRIPTIVE INFORMATION

De.1 Measure Title: Method of Adequacy Measurement for Pediatric Hemodialysis Patients

De.2 Brief description of measure*:* Percentage of pediatric (<18 years old) in-center HD patients (irrespective of frequency of dialysis) for whom delivered HD dose was measured by spKt/V as calculated using UKM or Daugirdas II during the reporting period

1.1-2 Type of Measure: Process
De.3 If included in a composite or paired with another measure, please identify composite or paired measure
Pediatric HD Adequacy - Frequency of Hemodialysis Adequacy Measurement

Pediatric HD Adequacy - Minimum Target spKt/V

De.4 National Priority Partners Priority Area: Population health
De.5 IOM Quality Domain: Effectiveness
De.6 Consumer Care Need: Living with illness

CONDITIONS FOR CONSIDERATION BY NQF	
Four conditions must be met before proposed measures may be considered and evaluated for suitability as voluntary consensus standards:	**NQF Staff**
A. The measure is in the public domain or an intellectual property (measure steward agreement) is signed. *Public domain only applies to governmental organizations. All non-government organizations must sign a measure steward agreement even if measures are made publicly and freely available.* **A.1 Do you attest that the measure steward holds intellectual property rights to the measure and the right to use aspects of the measure owned by another entity (e.g., risk model, code set)?** Yes **A.2 Indicate if Proprietary Measure** (*as defined in measure steward agreement*)**:** **A.3 Measure Steward Agreement:** Government entity and in the public domain - no agreement necessary **A.4 Measure Steward Agreement attached:**	**A** **Y**☐ **N**☐

B. The measure owner/steward verifies there is an identified responsible entity and process to maintain and update the measure on a schedule that is commensurate with the rate of clinical innovation, but at least every 3 years. Yes, information provided in contact section	**B** Y☐ N☐
C. The intended use of the measure includes both public reporting and quality improvement. ►**Purpose:** Public reporting, Internal quality improvement	**C** Y☐ N☐
D. The requested measure submission information is complete. Generally, measures should be fully developed and tested so that all the evaluation criteria have been addressed and information needed to evaluate the measure is provided. Measures that have not been tested are only potentially eligible for a time-limited endorsement and in that case, measure owners must verify that testing will be completed within 12 months of endorsement. D.1**Testing:** Yes, fully developed and tested D.2 **Have NQF-endorsed measures been reviewed to identify if there are similar or related measures?** Yes	**D** Y☐ N☐
(for NQF staff use) **Have all conditions for consideration been met?** **Staff Notes to Steward** (*if submission returned*)**:**	**Met** Y☐ N☐
Staff Notes to Reviewers (*issues or questions regarding any criteria*)**:**	
Staff Reviewer Name(s):	

TAP/Workgroup Reviewer Name:	
Steering Committee Reviewer Name:	
1. IMPORTANCE TO MEASURE AND REPORT	
Extent to which the specific measure focus is important to making significant gains in health care quality (safety, timeliness, effectiveness, efficiency, equity, patient-centeredness) and improving health outcomes for a specific high impact aspect of healthcare where there is variation in or overall poor performance. *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**	**Eval Rating**
(for NQF staff use) **Specific NPP goal**:	
1a.1 **Demonstrated High Impact Aspect of Healthcare:** Frequently performed procedure, Severity of illness 1a.2 1a.3 **Summary of Evidence of High Impact:** The incidence and prevalence rates of pediatric ESRD continue to increase with 7209 pediatric patients with ESRD in 2007 [1]. Although the majority of these patients are managed with kidney transplantation, approximately 2000 pediatric patients receive maintenance dialysis. Data also reveal that the five-year survival among pediatric patients receiving maintenance dialysis has not improved [1], demonstrating the need to improve the quality of dialysis care in this fragile patient group, particularly since no dialysis quality measures have been in place for the pediatric ESRD population. Finally, improving patient outcomes in pediatric patients is a priority particularly since the cost of care for a pediatric ESRD patient is markedly higher than for an adult patient [2]. The dose of dialysis is used to estimate the ability of hemodialysis to clear the blood of accumulated toxins. In the adult population, outcome studies have shown an association between dose of hemodialysis in terms of small solute removal and clinical outcomes [3,4]. No equivalent large scale clinical trials have been conducted in the pediatric hemodialysis population but smaller scale observational studies support the association between delivered hemodialysis dose and patient outcomes [5] including the potential for improved growth with intensive hemodialysis regimens [6,7].	**1a** C☐ P☐ M☐ N☐

Various methods for estimating urea clearance (Kt/V) were considered. Firstly, the second generation natural logarithmic (Daugirdas II formula) has been shown to approximate Kt/V obtained from formal urea kinetic modeling [8-10]. In addition, data from a single-center pediatric study showed that calculation of spKt/V using urea kinetic monitoring (UKM) or Daugirdas II was reliable [11]. The use of an equilibrated two-compartment model eKt/V was also evaluated. Although eKt/V has some advantage over spKt/V in that it takes into account urea rebound, data suggest a low rate of spKt/V and eKt/V discordance (defined as spKt/V > 0.2 higher than eKt/V) [12]. The use of standardized Kt/V was considered but not accepted due to potential difficulty in interpreting this metric as it is currently not widely used in patients receiving less than five times weekly hemodialysis. Surface area normalized Kt/V [13] was also considered but not included in the measure because this has not been studied in the pediatric population, and the implications of its use including the need for more frequent and intensified dialysis may not be feasible. Finally, the use of spKt/V as calculated using formal urea kinetic modeling or the Daugirdas II formula is consistent with clinical practice guidelines in the pediatric population, as well as with the clinical performance measures in the adult population.

1a.4 Citations for Evidence of High Impact:

1. U.S. Renal Data System, USRDS 2009 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, 2009.
2. Michael Leavitt, Secretary of Health and Human Services. A Design for a Bundled End-stage Renal Disease Prospective Payment System, Report to Congress, 2008.
3. Lowrie EG, et al. Effect of the hemodialysis prescription of patient morbidity:report from the National Cooperative Dialysis Study. N Engl J Med 305:1176–1181, 1981.
4. Owen WF Jr, et al. The urea reduction ratio and serum albumin concentration as predictors of mortality in patients undergoing hemodialysis. N Engl J Med 329:1001–1006, 1993.
5. Gorman G, et al. Clinical outcomes and dialysis adequacy in adolescent hemodialysis patients. Am Journal Kidney Dis; 47: 285-93, 2006.
6. Fischbach M, et al. Intensified and daily hemodialysis in children might improve statural growth. Pediatr Nephrol 21:1746–1752, 2006.
7. Tom A, et al. Growth during maintenance hemodialysis: impact of enhanced nutrition and clearance. J Pediatr. Apr;134(4):464-71, 1999.
8. Daugirdas JT, Greene T, Depner TA, Gotch FA, Star RA: Relationship between apparent (single-pool) and true (double-pool) urea distribution volume. Kidney Int 56:1928-1933, 1999.
9. Depner TA: Multi-compartment model, in Prescribing Hemodialysis: A Guide to Urea Modeling. Boston, MA, Kluwer, pp 91-126, 1999.
10. Daugirdas JT: Second generation logarithmic estimates of single-pool variable volume Kt/V: An analysis of error. J Am Soc Nephrol 4:1205-1213, 1993.
11. Goldstein SL, Brewer ED. Logarithmic extrapolation of a 15-minute postdialysis BUN to predict equilibriated BUN and calculate double-pool Kt/V in the pediatric hemodialysis population. Am J Kidney Dis: the official journal of the National Kidney foundation (2000) 36:98-104.
12. Goldstein SL, Brem A, Warady BA, et al. Comparison of single-pool and equilibrated Kt/V values for pediatric hemodialysis prescription management: analysis from the Centers for Medicare & Medicaid Services Clinical Performance Measures Project. Pediatric nephrology (Berlin, Germany) 21:1161-6, 2006.
13. John T. Daugirdas, Melisha G. Hanna, et al. Dose of dialysis based on body surface area is markedly less in younger children than in older adolescents. American Society of Nephrology, (2010 in press).

1b. Opportunity for Improvement

1b.1 Benefits (improvements in quality) envisioned by use of this measure: The dose of dialysis is used to estimate the ability of hemodialysis to clear the blood of accumulated toxins. In the pediatric population, smaller scale observational studies support the association between delivered hemodialysis dose and patient outcomes including the potential for improved growth with intensive hemodialysis regimens.

1b.2 Summary of data demonstrating performance gap (variation or overall poor performance) across providers:
The 2008 ESRD CPM project showed that among the random sample of 8,730 adults receiving hemodialysis, only 76% of patients had their delivered spKt/V calculated using either UKM or the Daugirdas II formula. Although this study is in the adult population, it is possible that similar findings may be observed in the pediatric ESRD population.

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1b.3 Citations for data on performance gap:
The 2008 ESRD CPM project can be found using the link below:
www.cms.hhs.gov/CPMProject.

1b.4 Summary of Data on disparities by population group:
In the North American Pediatric Renal Transplant Cooperative Study (NAPRTCS), monthly hemodialysis adequacy data were analyzed from 138 children from 32 centers. Multivariate modeling indicated that after adjusting for body surface area and lack of any Kt/V center measures, the mean Kt/V dose was significantly higher among females compared to males (ß=0.13, p<0.05) and among Nonblack patients compared to Black patients (ß=0.22, p<0.001).

1b.5 Citations for data on Disparities:
Leonard MB, et al. Racial and center differences in hemodialysis adequacy in children treated at pediatric centers: a North American Pediatric Renal Transplant Cooperative Study (NAPRTCS) report. J Am Soc Nephrol. 2004 Nov;15(11):2923-32

1c. Outcome or Evidence to Support Measure Focus

1c.1 Relationship to Outcomes (*For non-outcome measures, briefly describe the relationship to desired outcome. For outcomes, describe why it is relevant to the target population*)**:** Since pediatric patients are in a growth phase, a minimum of monthly evaluation of HD adequacy is critical to ensure timely dose adjustment as needed. The dose of dialysis is used to estimate the ability of hemodialysis to clear the blood of accumulated toxins. In the adult population, outcome studies have shown an association between dose of hemodialysis in terms of small solute removal and clinical outcomes [1,2]. No equivalent large scale clinical trials have been conducted in the pediatric hemodialysis population but smaller scale observational studies support the association between delivered hemodialysis dose as measured by spKt/V and patient outcomes [3] including the potential for improved growth with intensive hemodialysis regimens [4,5].

1c.2-3. Type of Evidence: Observational study, Evidence-based guideline

1c.4 Summary of Evidence (*as described in the criteria; for outcomes, summarize any evidence that healthcare services/care processes influence the outcome*)**:**
In the 2006 KDOQI Guidelines, Clinical Practice Guideline for pediatric hemodialysis adequacy (Guideline 8.2.1) indicates spKt/V, calculated by either formal urea kinetic modeling or the second-generation natural logarithm formula, should be used for month-to-month assessment of HD dose.
The second generation natural logarithmic (Daugirdas II formula) has been shown to approximate Kt/V obtained from formal urea kinetic modeling [6-8]. In addition, data from a single-center pediatric study showed that calculation of spKt/V using urea kinetic monitoring (UKM) or Daugirdas II was reliable [9].

1c.5 Rating of strength/quality of evidence (*also provide narrative description of the rating and by whom***):**
The pediatric adequacy clinical Technical Expert Panel (TEP) rated the strength of this measure as high.

1c.6 Method for rating evidence: The clinical TEP followed similar methods of evidence assessment as that used by the KDOQI Clinical Practice Guidelines.

1c.7 Summary of Controversy/Contradictory Evidence: The CTEP discussed alternative methods for measuring hemodialysis adequacy. Recent published data suggest the potential benefits of using surface-area normalized measures of hemodialysis adequacy because of concerns that methods based on the volume of distribution of urea (including spKt/V) may result in underdialysis of patients with smaller body weight (Daugirdas 2010). However, alternative methods for evaluating hemodialysis adequacy were not recommended by the TEP because these have not been extensively studied in the pediatric population, and the implications of the use of alternative measures, including the need for more frequent and intensified dialysis may not be feasible.

1c.8 Citations for Evidence (*other than guidelines***):** 1. Lowrie EG, et al. Effect of the hemodialysis prescription of patient morbidity:report from the National Cooperative Dialysis Study. N Engl J Med 305:1176–1181, 1981.

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2. Owen WF Jr, et al. The urea reduction ratio and serum albumin concentration as predictors of mortality in patients undergoing hemodialysis. N Engl J Med 329:1001–1006, 1993.
3. Gorman G, et al. Clinical outcomes and dialysis adequacy in adolescent hemodialysis patients. Am Journal Kidney Dis; 47: 285-93, 2006.
4. Fischbach M, et al. Intensified and daily hemodialysis in children might improve statural growth. Pediatr Nephrol 21:1746–1752, 2006.
5. Tom A, et al. Growth during maintenance hemodialysis: impact of enhanced nutrition and clearance. J Pediatr. Apr;134(4):464-71, 1999.

6. Daugirdas JT, Greene T, Depner TA, Gotch FA, Star RA: Relationship between apparent (single-pool) and true (double-pool) urea distribution volume. Kidney Int 56:1928-1933, 1999.

7. Depner TA: Multi-compartment model, in Prescribing Hemodialysis: A Guide to Urea Modeling. Boston, MA, Kluwer, pp 91-126, 1999.

8. Daugirdas JT: Second generation logarithmic estimates of single-pool variable volume Kt/V: An analysis of error. J Am Soc Nephrol 4:1205-1213, 1993.

9. Goldstein SL, Brewer ED. Logarithmic extrapolation of a 15-minute postdialysis BUN to predict equilibriated BUN and calculate double-pool Kt/V in the pediatric hemodialysis population. Am J Kidney Dis: the official journal of the National Kidney foundation (2000) 36:98-104.

10. John T. Daugirdas, Melisha G. Hanna, et al. Dose of dialysis based on body surface area is markedly less in younger children than in older adolescents. American Society of Nephrology, (2010 in press).

1c.9 Quote the Specific guideline recommendation (*including guideline number and/or page number***):**
GUIDELINE 8. PEDIATRIC HEMODIALYSIS PRESCRIPTION AND ADEQUACY
8.2.1.spKt/V, calculated by either formal urea kinetic modeling or the second-generation natural logarithm formula, should be used for month-to-month assessment of delivered HD dose. (B)

1c.10 Clinical Practice Guideline Citation: Clinical Practice Guidelines for Hemodialysis Adequacy: KDOQI Guideline 8. Pediatric Hemodialysis Prescription and Adequacy: 2006.
1c.11 National Guideline Clearinghouse or other URL: N/A

1c.12 Rating of strength of recommendation (*also provide narrative description of the rating and by whom***):**
KDOQI CPG 8.2.1 rating strength grade is 'B'. The recommendation for Grade B guidelines stats 'It is recommended that clinicians routinely follow the guideline for eligible patients. There is moderate to strong evidence that the practice improves health outcomes.'

1c.13 Method for rating strength of recommendation (*If different from USPSTF system, also describe rating and how it relates to USPSTF)***:**
The method used is the same as was used in developing the 2006 Kidney Disease Outcomes Quality Initiative (KDOQI) guidelines, in which experts decided which recommendations were supported by evidence and which were supported by consensus of Work Group opinion. Evidence-based guideline recommendations were graded as strong or moderate or weak. This approach is consistent with the U.S Preventive Services Task Force (USPSTF) grading method.

1c.14 Rationale for using this guideline over others:
Limited hemodialysis clinical practice guidelines exist for the pediatric population. In addition to the KDOQI clinical practice guidelines developed by the National Kidney Foundation, the 2005 CARI guidelines (Caring for Australians with Renal Impairment) also present guidelines for pediatric hemodialysis adequacy. The CARI guidelines present similar recommendations as the KDOQI, however, these guidelines are limited to providing recommendations for target spKt/V rather than method of measurement of hemodialysis adequacy.

TAP/Workgroup: What are the strengths and weaknesses in relation to the subcriteria for *Importance to Measure and Report?*	**1**

Steering Committee: Was the threshold criterion, *Importance to Measure and Report*, **met?** **Rationale:**	**1** **Y☐** **N☐**
2. 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)	**Eval Rating**
2a. MEASURE SPECIFICATIONS	
S.1 Do you have a web page where current detailed measure specifications can be obtained? **S.2 If yes, provide web page URL:** **2a. Precisely Specified**	
2a.1 Numerator Statement (*Brief, text description of the numerator - what is being measured about the target population, e.g. target condition, event, or outcome***):** Number of patients in the denominator for whom delivered HD dose for a single dialysis session was calculated using UKM or Daugirdas II during the reporting period and for whom the frequency of HD per week is specified. **2a.2 Numerator Time Window (***The time period in which cases are eligible for inclusion in the numerator***):** The entire calendar month. **2a.3 Numerator Details (***All information required to collect/calculate the numerator, including all codes, logic, and definitions***):** The numerator will be determined by counting the patients in the denominator for whom Kt/V "Hemodialysis Method" is ´Daugirdas II´ OR ´UKM´.	
2a.4 Denominator Statement (*Brief, text description of the denominator - target population being measured***):** Number of pediatric (<18 years old) in-center HD patients (irrespective of frequency of dialysis) in the sample for analysis. **2a.5 Target population gender:** Female, Male **2a.6 Target population age range:** Pediatric patients less than 18 years old **2a.7 Denominator Time Window (***The time period in which cases are eligible for inclusion in the denominator***):** The entire calendar month. **2a.8 Denominator Details (***All information required to collect/calculate the denominator - the target population being measured - including all codes, logic, and definitions***):** The patient's age will be determined by subtracting the patient's date of birth from the first day of the reporting month. In-center hemodialysis patients are defined as follows: "Admit Date" to the specified facility is prior or equal to the first day of the study period, AND the patient has not been discharged ("Discharge Date" is null or blank), OR "Discharge Date" from the facility is greater than or equal to the last day of the study period AND "Treatment Dialysis Broad Start Date" is prior or equal to the first day of the study period, AND "Dialysis Broad Type of Treatment" = ´HD´, AND "Primary Dialysis Setting" = ´Dialysis Facility/Center´ on the last day of the study period, AND "Date Regular Chronic Dialysis Began" is prior to the first day of the study period. The denominator will include all patients <18 years old who are determined to be in-center hemodialysis patients.	
2a.9 Denominator Exclusions (*Brief text description of exclusions from the target population***):** Patients on home dialysis, patients not in the facility for the entire calendar month. **2a.10 Denominator Exclusion Details (***All information required to collect exclusions to the denominator, including all codes, logic, and definitions***):** See denominator exclusions	**2a-specs** **C☐** **P☐** **M☐** **N☐**

2a.11 Stratification Details/Variables (*All information required to stratify the measure including the stratification variables, all codes, logic, and definitions***):**
No stratification is required for this measure.

2a.12-13 Risk Adjustment Type: No risk adjustment necessary

2a.14 Risk Adjustment Methodology/Variables (*List risk adjustment variables and describe conceptual models, statistical models, or other aspects of model or method***):**
N/A

2a.15-17 Detailed risk model available Web page URL or attachment:

2a.18-19 Type of Score: Rate/proportion
2a.20 Interpretation of Score: Better quality = Higher score
2a.21 Calculation Algorithm (*Describe the calculation of the measure as a flowchart or series of steps***):**
The patient's age will be determined by subtracting the patient's date of birth from the first day of the reporting month. In-center hemodialysis patients are defined as follows: "Admit Date" to the specified facility is prior or equal to the first day of the study period, AND the patient has not been discharged ("Discharge Date" is null or blank), OR "Discharge Date" from the facility is greater than or equal to the last day of the study period AND "Treatment Dialysis Broad Start Date" is prior or equal to the first day of the study period, AND "Dialysis Broad Type of Treatment" = ´HD´, AND "Primary Dialysis Setting" = ´Dialysis Facility/Center´ on the last day of the study period, AND "Date Regular Chronic Dialysis Began" is prior to the first day of the study period. The denominator will include all patients <18 years old who are determined to be in-center hemodialysis patients.
The numerator will be determined by counting the patients in the denominator for whom Kt/V "Hemodialysis Method" is ´Daugirdas II´ OR ´UKM´.

2a.22 Describe the method for discriminating performance *(e.g., significance testing)***:**
The performance of the facility will be compared to state, Network and national performance.

2a.23 Sampling (Survey) Methodology *If measure is based on a sample (or survey), provide instructions for obtaining the sample, conducting the survey and guidance on minimum sample size (response rate)*:
N/A

2a.24 Data Source (*Check the source(s) for which the measure is specified and tested)*
Electronic Health/Medical Record

2a.25 Data source/data collection instrument (*Identify the specific data source/data collection instrument, e.g. name of database, clinical registry, collection instrument, etc.***):**
CROWNWeb

2a.26-28 Data source/data collection instrument reference web page URL or attachment: URL
http://www.projectcrownweb.org/crown/index.php

2a.29-31 Data dictionary/code table web page URL or attachment: URL
http://www.projectcrownweb.org/crown/index.php?page=Public_Documents&subPage=Release_Documents

2a.32-35 Level of Measurement/Analysis (*Check the level(s) for which the measure is specified and tested)*
Facility/Agency

2a.36-37 Care Settings (*Check the setting(s) for which the measure is specified and tested)*
Dialysis Facility

2a.38-41 Clinical Services (*Healthcare services being measured, check all that apply*)
Dialysis

TESTING/ANALYSIS

2b. Reliability testing — **2b C☐**

2b.1 Data/sample *(description of data/sample and size)*: For the 2008 ESRD CPM project, inter-rater reliability was assessed using facility abstracted and Network re-abstracted data. A total of 301 randomly selected medical records were included in the analysis. (Centers for Medicare & Medicaid Services. 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). **2b.2 Analytic Method** *(type of reliability & rationale, method for testing)*: To analyze the inter-rater reliability of the ESRD CPM data agreement rates, levels of concurrence, and kappa statistics were computed. Agreement rates were calculated for continuous data, and kappa statistics and levels of concurrence were jointly used to analyze categorical data. **2b.3 Testing Results** *(reliability statistics, assessment of adequacy in the context of norms for the test conducted)*: Inter-rater reliability was tested for the method to calculate spKt/V. The kappa statistic for missing vs. non-missing values for October, November, and December ranged from 0.53 to 0.66. For non-missing data, kappa ranged from 0.79-0.80. Level of concurrence (LOC) for missing vs. non-missing for October, November and December ranged from 91%-93%, and for non-missing data only was 86-87%. Generally, acceptable agreement rates are 0.80 or higher and concurrence targets are 90% or higher.	**P**☐ **M**☐ **N**☐
2c. Validity testing **2c.1 Data/sample** *(description of data/sample and size)*: This measure was established on the basis of face validity. All clinical TEP members agreed that this measure will improve quality of care for pediatric in-center hemodialysis patients. **2c.2 Analytic Method** *(type of validity & rationale, method for testing)*: Face validity is the only validity assessed, as there is no gold standard for defining the method of measuring hemodialysis adequacy in the pediatric population. **2c.3 Testing Results** *(statistical results, assessment of adequacy in the context of norms for the test conducted)*: N/A	**2c** **C**☐ **P**☐ **M**☐ **N**☐
2d. Exclusions Justified **2d.1 Summary of Evidence supporting exclusion(s):** Exclusions are not supported by evidence. However, they are limited to those with a compelling clinical rationale and are precisely defined. **2d.2 Citations for Evidence:** N/A **2d.3 Data/sample** *(description of data/sample and size)*: N/A **2d.4 Analytic Method** *(type analysis & rationale)*: N/A **2d.5 Testing Results** *(e.g., frequency, variability, sensitivity analyses)*: N/A	**2d** **C**☐ **P**☐ **M**☐ **N**☐ **NA**☐
2e. Risk Adjustment for Outcomes/ Resource Use Measures **2e.1 Data/sample** *(description of data/sample and size)*: No risk adjustments are necessary for this measure. **2e.2 Analytic Method** *(type of risk adjustment, analysis, & rationale)*: No risk adjustments are necessary for this measure. **2e.3 Testing Results** *(risk model performance metrics)*:	**2e** **C**☐ **P**☐ **M**☐ **N**☐ **NA**☐

No risk adjustments are necessary for this measure. **2e.4 If outcome or resource use measure is not risk adjusted, provide rationale:** No risk adjustments are necessary for this measure.	
2f. Identification of Meaningful Differences in Performance **2f.1 Data/sample from Testing or Current Use** *(description of data/sample and size)*: Data from the ESRD CPM Project were used to perform analyses on determining differences in performance in the hemodialysis facilities. In the 2008 study, CPM data were collected on all pediatric hemodialysis patients from October 2007 through December 2007. A total of 693 pediatric hemodialysis patients were analyzed from 252 facilities. **2f.2 Methods to identify statistically significant and practically/meaningfully differences in performance** *(type of analysis & rationale)*: Facility level performance was evaluated using descriptive statistics including facility level percentages. **2f.3 Provide Measure Scores from Testing or Current Use** *(description of scores, e.g., distribution by quartile, mean, median, SD, etc.; identification of statistically significant and meaningfully differences in performance)*: Of the 252 facilities with hemodialysis pediatric patients, only 207 (82%) reported the method of Kt/V measurement in all three reporting months. Of these facilities, 30% reported using methods other than UKM or Daugirdas II for all pediatric hemodialysis patients.	**2f** C☐ P☐ M☐ N☐
2g. Comparability of Multiple Data Sources/Methods **2g.1 Data/sample** *(description of data/sample and size)*: CROWNWeb. Phase 1 and 2 CROWNWeb Beta Testing Data: Data are based on the 18 facilities participating in Phase 1 and the 180 facilities participating in Phase 2 plus about 3000 additional batch-submission facilities in CROWNWeb. These data include about 60% of dialysis facilities and 75% of dialysis patients and are heavily weighted towards large dialysis organization facilities. **2g.2 Analytic Method** *(type of analysis & rationale)*: Multiple data sources are not allowed for this measure, and therefore testing is not applicable. **2g.3 Testing Results** *(e.g., correlation statistics, comparison of rankings)*: N/A	**2g** C☐ P☐ M☐ N☐ NA☐
2h. Disparities in Care **2h.1 If measure is stratified, provide stratified results** *(scores by stratified categories/cohorts)*: N/A **2h.2 If disparities have been reported/identified, but measure is not specified to detect disparities, provide follow-up plans:** Will consider stratification by gender, race and age given the prior report that suggests disparities in achieved Kt/V by these demographic factors.	**2h** C☐ P☐ M☐ N☐ NA☐
TAP/Workgroup: What are the strengths and weaknesses in relation to the subcriteria for *Scientific Acceptability of Measure Properties?*	**2**
Steering Committee: Overall, to what extent was the criterion, *Scientific Acceptability of Measure Properties*, **met?** **Rationale:**	*2* C☐ P☐ M☐ N☐
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)	**Eval Rating**
3a. Meaningful, Understandable, and Useful Information	**3a** C☐

3a.1 Current Use: Not in use but testing completed **3a.2 Use in a public reporting initiative (disclosure of performance results to the public at large)** (*If used in a public reporting initiative, provide name of initiative(s), locations, Web page URL(s). If not publicly reported, state the plans to achieve public reporting within 3 years*)**:** This measure currently applies to the adult hemodialysis population. Results from the adult CPM can be found in the ESRD Clinical Performance Measures Project. URL: www.cms.hhs.gov/CPMProject. **3a.3 If used in other programs/initiatives (***If used in quality improvement or other programs/initiatives, name of initiative(s), locations, Web page URL(s). If not used for QI, state the plans to achieve use for QI within 3 years***):** The NAPRTCS (North American Pediatric Renal Transplant Cooperative Study) is a voluntary initiative of pediatric ESRD treatment facilities to report transplantation and dialysis outcomes. The NAPRTCS has provided analysis on hemodialysis adequacy in prior annual reports as shown in the following citation: Leonard MB, et al. Racial and center differences in hemodialysis adequacy in children treated at pediatric centers: a North American Pediatric Renal Transplant Cooperative Study (NAPRTCS) report. J Am Soc Nephrol. 2004 Nov;15(11):2923-32. **Testing of Interpretability** (*Testing that demonstrates the results are understood by the potential users for public reporting and quality improvement*) **3a.4 Data/sample** *(description of data/sample and size)***:** Formal testing of interpretability has not been performed. **3a.5 Methods** *(e.g., focus group, survey, QI project)***:** N/A **3a.6 Results** *(qualitative and/or quantitative results and conclusions)***:** N/A	**P☐** **M☐** **N☐**
3b/3c. Relation to other NQF-endorsed measures **3b.1 NQF # and Title of similar or related measures:** NQF # 0248ESRD- HD Adequacy CPM II: Method of measurement of delivered hemodialysis dose.	
(for NQF staff use) **Notes on similar/related endorsed or submitted measures:**	
3b. Harmonization If this measure is related to measure(s) already endorsed by NQF (e.g., same topic, but different target population/setting/data source or different topic but same target population): **3b.2 Are the measure specifications harmonized? If not, why?** This proposed measure is harmonized with the adult measure.	**3b** **C☐** **P☐** **M☐** **N☐** **NA☐**
3c. Distinctive or Additive Value **3c.1 Describe the distinctive, improved, or additive value this measure provides to existing NQF-endorsed measures:** This measure is for pediatric (<18 years) patients only. The NQF endorsed measure is for patients>=18 years old. **5.1 If this measure is similar to measure(s) already endorsed by NQF (i.e., on the same topic and the same target population), Describe why it is a more valid or efficient way to measure quality:** This measure is for pediatric (<18 years) patients only. The NQF endorsed measure is for patients>=18 years old.	**3c** **C☐** **P☐** **M☐** **N☐** **NA☐**
TAP/Workgroup: What are the strengths and weaknesses in relation to the subcriteria for *Usability*?	**3**
Steering Committee: Overall, to what extent was the criterion, *Usability***, met?** **Rationale:**	**3** **C☐** **P☐** **M☐**

	N☐
4. FEASIBILITY	
Extent to which the required data are readily available, retrievable without undue burden, and can be implemented for performance measurement. (evaluation criteria)	**Eval Rating**
4a. Data Generated as a Byproduct of Care Processes 4a.1-2 **How are the data elements that are needed to compute measure scores generated?** Data generated as byproduct of care processes during care delivery (Data are generated and used by healthcare personnel during the provision of care, e.g., blood pressure, lab value, medical condition)	**4a** C☐ P☐ M☐ N☐
4b. Electronic Sources 4b.1 **Are all the data elements available electronically?** (*elements that are needed to compute measure scores are in defined, computer-readable fields, e.g., electronic health record, electronic claims*) Yes 4b.2 **If not, specify the near-term path to achieve electronic capture by most providers.**	**4b** C☐ P☐ M☐ N☐
4c. Exclusions 4c.1 **Do the specified exclusions require additional data sources beyond what is required for the numerator and denominator specifications?** No 4c.2 **If yes, provide justification.**	**4c** C☐ P☐ M☐ N☐ NA☐
4d. Susceptibility to Inaccuracies, Errors, or Unintended Consequences 4d.1 **Identify susceptibility to inaccuracies, errors, or unintended consequences of the measure and describe how these potential problems could be audited. If audited, provide results.** Data elements for this measure are already being collected and are unlikely to be susceptible to inaccuracies, errors or unintended consequences.	**4d** C☐ P☐ M☐ N☐
4e. Data Collection Strategy/Implementation 4e.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/frequency of data collection, patient confidentiality, time/cost of data collection, other feasibility/ implementation issues:** Because data elements required for this measure are already being collected as part of the ESRD CPM, facilities are familiar with data required for this measure. This reduces the likelihood of errors in the data collection process. 4e.2 **Costs to implement the measure** (*costs of data collection, fees associated with proprietary measures*)**:** The estimated data collection burden and associated cost estimate is presented in Tables 1-3 in the Federal Register. Vol. 73, No. 73 page 20469. URL:http://www.cms.gov/CFCsAndCoPs/downloads/ESRDfinalrule0415.pdf 4e.3 **Evidence for costs:** See above reference to Federal Register. 4e.4 **Business case documentation:** No studies have formally evaluated the cost-effectiveness of routine measurement of spKt/V in the pediatric population. However, published clinical studies suggest that low spKt/V as a measure of hemodialysis adequacy is associated with increased risk of hospitalization. For instance, adolescents with spKt/V below 1.2 were found to have significantly increased risk of hospitalization as compared to those with spKt/V of 1.2-1.4 [1]. Since hospital admissions are associated	**4e** C☐ P☐ M☐ N☐

with increased cost, efforts to reduce hospitalization, including improving adequacy of hemodialysis treatments may potentially result in cost-savings. 1. Gorman G, et al. Clinical outcomes and dialysis adequacy in adolescent hemodialysis patients. Am Journal Kidney Dis; 47: 285-93, 2006.	
TAP/Workgroup: What are the strengths and weaknesses in relation to the subcriteria for *Feasibility*?	**4**
Steering Committee: Overall, to what extent was the criterion, *Feasibility*, **met?** **Rationale:**	**4** **C☐** **P☐** **M☐** **N☐**
RECOMMENDATION	
(for NQF staff use) **Check if measure is untested and only eligible for time-limited endorsement.**	**Time-limited ☐**
Steering Committee: Do you recommend for endorsement? **Comments:**	**Y☐** **N☐** **A☐**

CONTACT INFORMATION

Co.1 Measure Steward (Intellectual Property Owner)
Co.1 Organization
Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, Maryland, 21244

Co.2 Point of Contact
Thomas, Dudley, Thomas.Dudley@cms.hhs.gov, 410-786-1442-

Measure Developer If different from Measure Steward
Co.3 Organization
Arbor Research/UM-KECC, 315 W. Huron, Suite 360, Ann Arbor, Michigan, 48103

Co.4 Point of Contact
Adrienne, Janney, adrienne.janney@arborresearch.org, 734-665-4108-

Co.5 Submitter If different from Measure Steward POC
Thomas, Dudley, Thomas.Dudley@cms.hhs.gov, 410-786-1442-, Centers for Medicare & Medicaid Services

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

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.
Dr. Bradley Warady, panel chair (University of Missouri, Kansas City School of Medicine, Kansas City, MO)
Dr. Carolyn Abitbol (University of Miami, Holtz Children's Hospital, Miami, FL)
Dr. Eileen Brewer (Baylor College of Medicine/Texas Children's Hospital, Houston, TX)
Dr. Stuart Goldstein (Baylor College of Medicine/Texas Children's Hospital, Houston, TX)
Dr. Alicia Neu (Johns Hopkins Medical Institution, Baltimore, MD)
Dr. Irene Restaino (Children's Hospital of The King Daughters, Norfolk, VA)
Dr. Douglas Silverstein (Children´s National Medical Center, Washington, D.C.)
Dr. Sylvia Ramirez, Moderator (Arbor Research Collaborative for Health)
Alissa Kapke, Analyst, (Arbor Research Collaborative for Health)
Jeffrey Pearson, Analytical Manager, (Arbor Research Collaborative for Health)

Ad.2 If adapted, provide name of original measure:
Ad.3-5 If adapted, provide original specifications URL or attachment

Measure Developer/Steward Updates and Ongoing Maintenance **Ad.6 Year the measure was first released:** **Ad.7 Month and Year of most recent revision:** **Ad.8 What is your frequency for review/update of this measure?** Three years **Ad.9 When is the next scheduled review/update for this measure?** 2013
Ad.10 Copyright statement/disclaimers:
Ad.11 -13 Additional Information web page URL or attachment:
Date of Submission (*MM/DD/YY*)**:** 03/03/2011