

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 #: 1425	NQF Project: End Stage Renal Disease
MEASURE DESCRIPTIVE INFORMATION	
De.1 Measure Title: Measurement of nPCR 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) with documented monthly nPCR measurements	
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 N/A	
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
<p>A. The measure is in the public domain or an intellectual property (measure steward agreement) is signed. <i>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.</i></p> <p>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</p> <p>A.2 Indicate if Proprietary Measure (as defined in measure steward agreement):</p> <p>A.3 Measure Steward Agreement: Government entity and in the public domain - no agreement necessary</p> <p>A.4 Measure Steward Agreement attached:</p>	<p>A</p> <p>Y <input type="checkbox"/></p> <p>N <input type="checkbox"/></p>
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	<p>B</p> <p>Y <input type="checkbox"/></p>

every 3 years. Yes, information provided in contact section	N <input type="checkbox"/>
C. The intended use of the measure includes <u>both</u> public reporting <u>and</u> quality improvement. ► Purpose: Public reporting, Internal quality improvement	C Y <input type="checkbox"/> N <input type="checkbox"/>
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: No, testing will be completed within 12 months D.2 Have NQF-endorsed measures been reviewed to identify if there are similar or related measures? Yes	D Y <input type="checkbox"/> N <input type="checkbox"/>
(for NQF staff use) Have all conditions for consideration been met? Staff Notes to Steward (<i>if submission returned</i>):	Met Y <input type="checkbox"/> N <input type="checkbox"/>
Staff Notes to Reviewers (<i>issues or questions regarding any criteria</i>):	
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. <i>Measures must be judged to be important to measure and report in order to be evaluated against the remaining criteria.</i> (evaluation criteria) 1a. High Impact	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]. In the pediatric population, the assessment of dialysis adequacy requires an evaluation of both small solute clearance and nutritional status [3, 4]. This is because both adequate solute clearance and nutrition are essential for growth and visceral weight gain. Whereas there are several potential measures of nutritional status, these are outside the scope of hemodialysis adequacy measures with the exception of nPCR (normalized protein catabolic rate), a value that is a fundamental component of and already readily available from urea kinetics. This allows the use of nPCR along with spKt/V as measures of dialysis adequacy.	1a C <input type="checkbox"/> P <input type="checkbox"/> M <input type="checkbox"/> N <input type="checkbox"/>

<p>nPCR provides an estimate of dietary protein intake and has been shown to provide additional information to spKt/V. In malnourished adolescent patients who achieved target spKt/V levels, nPCR, but not serum albumin, was associated with nutritional status [5, 6]. In adolescent patients, nPCR levels < 1 gram/kg/day were found to be an earlier and more sensitive marker than serum albumin levels in predicting malnutrition and sustained weight loss [7]. There is currently no evidence that supports specific nPCR targets, although age-specific protein intake targets exist. The same data needed for Kt/V calculation can be used for nPCR calculation. Thus, nPCR can be monitored monthly along with Kt/V to follow up protein intake for a particular patient.</p> <p>1a.4 Citations for Evidence of High Impact:</p> <ol style="list-style-type: none"> 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. Clinical Practice Guidelines for Hemodialysis Adequacy: KDOQI Guideline 8. Pediatric Hemodialysis Prescription and Adequacy: 2006. 4. Clinical Practice Guideline for Nutrition in Children with CKD: 2008 Update, Recommendation 1. 5. Goldstein, Baronette, et al. nPCR assessment and IDPN treatment of malnutrition in pediatric hemodialysis patients. Pediatric Nephrology (2002) 17:531-534. 6. Orellana P, Juarez-Congelosi M, Goldstein SL. Intradialytic parenteral nutrition treatment and biochemical marker assessment for malnutrition in adolescent maintenance hemodialysis patients. J Ren Nutrition 2005 Jul;15(3):312-7. 7. Juarez-Congelosi M, Orellana P, Goldstein SL: Normalized protein catabolic rate versus serum albumin as a nutrition status marker in pediatric patients receiving hemodialysis. J Ren Nutr 17:269-274, 2007. 	
<p>1b. Opportunity for Improvement</p> <p>1b.1 Benefits (improvements in quality) envisioned by use of this measure: nPCR provides an estimate of dietary protein intake and has been shown to provide additional information to spKt/V. Studies have shown that in adolescent patients who achieved target spKt/V levels, nPCR was associated with nutritional status. Furthermore, there is evidence that nPCR < 1 gram/kg/day is predictive of malnutrition and sustained weight loss among adolescent patients.</p> <p>1b.2 Summary of data demonstrating performance gap (variation or overall poor performance) across providers: The same data needed for Kt/V calculation are used for nPCR calculation. There has been no systematic effort by clinicians to collect nPCR values and there is no current evidence demonstrating performance gap. However, given the high incidence of malnutrition in the ESRD population, and the increased nutritional requirements particularly in the pediatric ESRD patient, clinical guidelines recommend monthly measurement of nutritional markers in the ESRD population. In an online survey over 200 renal dietitians conducted by the Council of Renal Nutrition (CRN) on behalf of the Dialysis Outcomes and Practice Patterns Study (DOPPS), only 32% reported monitoring of dietary intake at the recommended interval by clinical guidelines. Thus, though no published data are current available demonstrating performance gap, there is clinical evidence that measurement of nutritional status in this population may not be performed routinely.</p> <p>1b.3 Citations for data on performance gap: Unpublished survey as presented above.</p> <p>1b.4 Summary of Data on disparities by population group: None available, nPCR measurements have not been systematically evaluated in the adult or pediatric populations.</p> <p>1b.5 Citations for data on Disparities: N/A</p>	<p>1b</p> <p>C <input type="checkbox"/></p> <p>P <input type="checkbox"/></p> <p>M <input type="checkbox"/></p> <p>N <input type="checkbox"/></p>
<p>1c. Outcome or Evidence to Support Measure Focus</p> <p>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): Small observational studies</p>	<p>1c</p> <p>C <input type="checkbox"/></p> <p>P <input type="checkbox"/></p> <p>M <input type="checkbox"/></p>

have found nPCR to be associated with malnutrition and sustained weight loss.

N

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 Kidney Disease Outcomes Quality Initiative (KDOQI) Guidelines, Clinical Practice Guideline for pediatric hemodialysis adequacy (Guideline 8.2.2) specifies nPCR should be measured monthly. The 2008 KDOQI Clinical Practice Guideline Update for nutrition in children with CKD Recommendation 1.1 states that the nutritional status and growth of all children with CKD stages 2-5 be evaluated on a periodic basis. Recommendation 1.2 states that nPCR should be evaluated in hemodialyzed adolescents.

Small scale observational studies have shown an association between nPCR and nutritional status among malnourished adolescent patients who achieved target spKt/V levels [1,2]. Additionally, in adolescent patients, nPCR levels < 1 gram/kg/day were found to be an earlier and more sensitive marker than serum albumin levels in predicting malnutrition and sustained weight loss [3].

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 that although there is currently no evidence that supports specific nPCR targets in the pediatric hemodialysis population, age-specific protein intake targets exist. Furthermore, nPCR levels in particular patient are intended to be tracked over time to evaluate appropriateness of protein intake.

1c.8 Citations for Evidence (*other than guidelines*): 1. Goldstein, Baronette, et al. nPCR assessment and IDPN treatment of malnutrition in pediatric hemodialysis patients. *Pediatric Nephrology* (2002) 17:531-534. 2. Orellana P, Juarez-Congelosi M, Goldstein SL. Intradialytic parenteral nutrition treatment and biochemical marker assessment for malnutrition in adolescent maintenance hemodialysis patients. *J Ren Nutrition* 2005 Jul;15(3):312-7. 3. Juarez-Congelosi M, Orellana P, Goldstein SL: Normalized protein catabolic rate versus serum albumin as a nutrition status marker in pediatric patients receiving hemodialysis. *J Ren Nutr* 17:269-274, 2007.

1c.9 Quote the Specific guideline recommendation (*including guideline number and/or page number*):

2006 KDOQI GUIDELINE 8. PEDIATRIC HEMODIALYSIS PRESCRIPTION AND ADEQUACY

8.2.2 Assessment of nutrition status is an essential component of HD adequacy measurement. nPCR should be measured monthly by using either formal urea kinetic modeling or algebraic approximation. (B)

2008 KDOQI CPR RECOMMENDATION 1: EVALUATION OF GROWTH AND NUTRITIONAL STATUS

1.1 The nutritional status and growth of all children with CKD stages 2 to 5 and 5D should be evaluated on a periodic basis. (A)

1.2 The following parameters of nutritional status and growth should be considered in combination for evaluation in children with CKD stages 2 to 5 and 5D. (B)

- i. Dietary intake (3-day diet record or three 24-hour dietary recalls)
- ii Length- or height-for-age percentile or standard deviation score(SDS)
- iii Length or height velocity-for-age percentile or SDS
- iv Estimated dry weight and weight-for-age percentile or SDS
- v BMI-for-height-age percentile or SDS
- vi Head circumference-for-age percentile or SDS (=3 years old only)
- vii Normalized protein catabolic rate (nPCR) in hemodialyzed adolescents with CKD stage 5D.

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

<p>1c.12 Rating of strength of recommendation (<i>also provide narrative description of the rating and by whom</i>): The 2006 KDOQI Guideline 8.2.2 rating strength grade is 'B'. The recommendation for Grade B guidelines states 'It is recommended that clinicians routinely follow the guideline for eligible patients. There is moderate to strong evidence that the practice improves health outcomes.'</p> <p>1c.13 Method for rating strength of recommendation (<i>If different from USPSTF system, also describe rating and how it relates to USPSTF</i>): The method used is the same as was used in developing the 2006 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 USPSTF grading method.</p> <p>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 measurement of nPCR.</p>	
<p>TAP/Workgroup: What are the strengths and weaknesses in relation to the subcriteria for <i>Importance to Measure and Report</i>?</p>	<p>1</p>
<p>Steering Committee: Was the threshold criterion, <i>Importance to Measure and Report</i>, met? Rationale:</p>	<p>1 Y <input type="checkbox"/> N <input type="checkbox"/></p>
<p>2. SCIENTIFIC ACCEPTABILITY OF MEASURE PROPERTIES</p>	
<p>Extent to which the measure, <u>as specified</u>, produces consistent (reliable) and credible (valid) results about the quality of care when implemented. (evaluation criteria)</p>	<p>Eval Rating</p>
<p>2a. MEASURE SPECIFICATIONS</p>	
<p>S.1 Do you have a web page where current detailed measure specifications can be obtained? S.2 If yes, provide web page URL:</p> <p>2a. Precisely Specified</p>	
<p>2a.1 Numerator Statement (<i>Brief, text description of the numerator - what is being measured about the target population, e.g. target condition, event, or outcome</i>): Number of patients in the denominator with monthly nPCR measurements.</p> <p>2a.2 Numerator Time Window (<i>The time period in which cases are eligible for inclusion in the numerator</i>): The entire calendar month.</p> <p>2a.3 Numerator Details (<i>All information required to collect/calculate the numerator, including all codes, logic, and definitions</i>): The numerator will be determined by counting the patients in the denominator who meet one of the following criteria during the study month: npCR is populated AND "Date nPCR Collected" is populated, OR "Kt/V Hemodialysis Collection Date" is populated, AND "BUN Pre-Dialysis" is populated, AND "BUN Post-Dialysis" is populated, AND "Pre-Dialysis Weight" is populated, AND "Pre-Dialysis Weight Unit of Measure" is populated, AND "Post-Dialysis Weight" is populated, AND "Post-Dialysis Weight Unit of Measure" is populated, AND "Delivered Minutes of BUN Hemodialysis Session" is populated AND "Interdialytic Time" is populated.</p>	<p>2a- specs C <input type="checkbox"/> P <input type="checkbox"/> M <input type="checkbox"/> N <input type="checkbox"/></p>
<p>2a.4 Denominator Statement (<i>Brief, text description of the denominator - target population being measured</i>): Number of all pediatric (<18 years old) in-center hemodialysis patients (irrespective of frequency of dialysis).</p>	

2a.5 Target population gender: Female, Male

2a.6 Target population age range: Pediatric patients 18 years or younger.

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 duration of hemodialysis treatment will be calculated as the difference between the first "Kt/V Collection Date" and "Date Regular Chronic Dialysis Began". The denominator will include all in-center hemodialysis patients <18 years old. 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.

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 one-month study period.

2a.10 Denominator Exclusion Details (*All information required to collect exclusions to the denominator, including all codes, logic, and definitions*):

See denominator exclusions.

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 duration of hemodialysis treatment will be calculated as the difference between the first "Kt/V Collection Date" and "Date Regular Chronic Dialysis Began". The denominator will include all in-center hemodialysis patients <18 years old. 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 numerator will be determined by counting the patients in the denominator who meet one of the following criteria during the study month: npCR is populated AND "Date npCR Collected" is populated, OR "Kt/V Hemodialysis Collection Date" is populated, AND "BUN Pre-Dialysis" is populated, AND "BUN Post-Dialysis" is populated, AND "Pre-Dialysis Weight" is populated, AND "Pre-Dialysis Weight Unit of Measure" is populated, AND "Post-Dialysis Weight" is populated, AND "Post-Dialysis Weight Unit of Measure" is populated, AND "Delivered Minutes of BUN Hemodialysis Session" is populated AND "Interdialytic Time" is populated.

<p>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.</p>	
<p>2a.23 Sampling (Survey) Methodology <i>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):</i> N/A</p>	
<p>2a.24 Data Source (Check the source(s) for which the measure is specified and tested) Electronic clinical data</p>	
<p>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</p>	
<p>2a.26-28 Data source/data collection instrument reference web page URL or attachment: URL http://www.projectcrownweb.org/crown/index.php</p>	
<p>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</p>	
<p>2a.32-35 Level of Measurement/Analysis (Check the level(s) for which the measure is specified and tested) Facility/Agency</p>	
<p>2a.36-37 Care Settings (Check the setting(s) for which the measure is specified and tested) Dialysis Facility</p>	
<p>2a.38-41 Clinical Services (Healthcare services being measured, check all that apply) Dialysis</p>	
TESTING/ANALYSIS	
<p>2b. Reliability testing</p>	
<p>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)</p>	
<p>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.</p>	
<p>2b.3 Testing Results (reliability statistics, assessment of adequacy in the context of norms for the test conducted): Reliability of nPCR measures has not been assessed. However, since the components for measurement of nPCR are the same as Kt/V, reliability statistics for nPCR should be the same as Kt/V. For weekly Kt/V=1.2, the average Kappa statistic (of October, November, and December) for non-missing data ranged from 0.94 to 0.96. The average level of concurrence (LOC) for non-missing data was 100%. Generally, acceptable agreement rates are 0.80 or higher and concurrence targets are 90% or higher.</p>	<p>2b C <input type="checkbox"/> P <input type="checkbox"/> M <input type="checkbox"/> N <input type="checkbox"/></p>
<p>2c. Validity testing</p>	
<p>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.</p>	<p>2c C <input type="checkbox"/> P <input type="checkbox"/> M <input type="checkbox"/> N <input type="checkbox"/></p>

<p>2c.2 Analytic Method (<i>type of validity & rationale, method for testing</i>): Face validity is the only validity assessed, as there is no gold standard for defining the frequency of measurement of nPCR in the pediatric hemodialysis population.</p> <p>2c.3 Testing Results (<i>statistical results, assessment of adequacy in the context of norms for the test conducted</i>): N/A</p>	
<p>2d. Exclusions Justified</p> <p>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.</p> <p>2d.2 Citations for Evidence: N/A</p> <p>2d.3 Data/sample (<i>description of data/sample and size</i>): N/A</p> <p>2d.4 Analytic Method (<i>type analysis & rationale</i>): N/A</p> <p>2d.5 Testing Results (<i>e.g., frequency, variability, sensitivity analyses</i>): N/A</p>	<p>2d</p> <p>C <input type="checkbox"/></p> <p>P <input type="checkbox"/></p> <p>M <input type="checkbox"/></p> <p>N <input type="checkbox"/></p> <p>NA <input type="checkbox"/></p>
<p>2e. Risk Adjustment for Outcomes/ Resource Use Measures</p> <p>2e.1 Data/sample (<i>description of data/sample and size</i>): No risk adjustments are necessary for this measure.</p> <p>2e.2 Analytic Method (<i>type of risk adjustment, analysis, & rationale</i>): N/A</p> <p>2e.3 Testing Results (<i>risk model performance metrics</i>): N/A</p> <p>2e.4 If outcome or resource use measure is not risk adjusted, provide rationale: N/A</p>	<p>2e</p> <p>C <input type="checkbox"/></p> <p>P <input type="checkbox"/></p> <p>M <input type="checkbox"/></p> <p>N <input type="checkbox"/></p> <p>NA <input type="checkbox"/></p>
<p>2f. Identification of Meaningful Differences in Performance</p> <p>2f.1 Data/sample from Testing or Current Use (<i>description of data/sample and size</i>): 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.</p> <p>2f.2 Methods to identify statistically significant and practically/meaningfully differences in performance (<i>type of analysis & rationale</i>): Although nPCR measurement has not been tested and is not in current use, the components for measurement of nPCR are the same as spKt/V. Therefore, facility level percentages of monthly spKt/V reporting were evaluated.</p> <p>2f.3 Provide Measure Scores from Testing or Current Use (<i>description of scores, e.g., distribution by quartile, mean, median, SD, etc.; identification of statistically significant and meaningfully differences in performance</i>): Facility level data showed only 52% of facilities with pediatric patients reported Kt/V for all three of the reporting months. A total of 30 (12%) facilities did not report Kt/V in any of the three reporting months for any of their pediatric hemodialysis patients. The recommended level for nPCR is =1.0 g/kg/day, and patients are considered malnourished when nPCR<0.8 g/kg/day. Using the modified Borah equation for calculating nPCR levels and averaging over 8</p>	<p>2f</p> <p>C <input type="checkbox"/></p> <p>P <input type="checkbox"/></p> <p>M <input type="checkbox"/></p> <p>N <input type="checkbox"/></p>

<p>months of data collected in CROWNWeb (from July 2009 through February 2010), 50.7% of patients had a mean nPCR of 1.0 or higher. This suggests that a significant proportion of patients do not achieve the recommended target nPCR level.</p>	
<p>2g. Comparability of Multiple Data Sources/Methods</p> <p>2g.1 Data/sample (<i>description of data/sample and size</i>): 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.</p> <p>2g.2 Analytic Method (<i>type of analysis & rationale</i>): Multiple data sources are not allowed for this measure, and therefore testing is not needed.</p> <p>2g.3 Testing Results (<i>e.g., correlation statistics, comparison of rankings</i>): N/A</p>	<p>2g C <input type="checkbox"/> P <input type="checkbox"/> M <input type="checkbox"/> N <input type="checkbox"/> NA <input type="checkbox"/></p>
<p>2h. Disparities in Care</p> <p>2h.1 If measure is stratified, provide stratified results (<i>scores by stratified categories/cohorts</i>): N/A</p> <p>2h.2 If disparities have been reported/identified, but measure is not specified to detect disparities, provide follow-up plans: N/A</p>	<p>2h C <input type="checkbox"/> P <input type="checkbox"/> M <input type="checkbox"/> N <input type="checkbox"/> NA <input type="checkbox"/></p>
<p>TAP/Workgroup: What are the strengths and weaknesses in relation to the subcriteria for <i>Scientific Acceptability of Measure Properties</i>?</p>	<p>2</p>
<p>Steering Committee: Overall, to what extent was the criterion, <i>Scientific Acceptability of Measure Properties</i>, met? Rationale:</p>	<p>2 C <input type="checkbox"/> P <input type="checkbox"/> M <input type="checkbox"/> N <input type="checkbox"/></p>
3. USABILITY	
<p>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)</p>	<p>Eval Rating</p>
<p>3a. Meaningful, Understandable, and Useful Information</p> <p>3a.1 Current Use: Testing not yet completed</p> <p>3a.2 Use in a public reporting initiative (disclosure of performance results to the public at large) (<i>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</i>): This is currently not publically reported. This measure could be considered for public reporting on Medicare's Dialysis Facility Compare website in the future.</p> <p>3a.3 If used in other programs/initiatives (<i>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</i>): A small number of pediatric hemodialysis units have reported routine measurement of nPCR (Goldstein, Baronette, et al. nPCR assessment and IDPN treatment of malnutrition in pediatric hemodialysis patients. <i>Pediatric Nephrology</i> (2002) 17:531-534; Silverstein et al. Assessment of relationship between nutrition and growth in pediatric hemodialysis patients. <i>J Ren Nutr.</i> 2009 Sep;19(5):422-31).</p> <p>Testing of Interpretability (<i>Testing that demonstrates the results are understood by the potential users for public reporting and quality improvement</i>)</p> <p>3a.4 Data/sample (<i>description of data/sample and size</i>): No specific testing for interpretability of this measure has been done. However, nPCR has been used to track protein intake and to evaluate patient response to interdialytic parenteral nutrition (Goldstein, Baronette, et al. nPCR assessment and IDPN</p>	<p>3a C <input type="checkbox"/> P <input type="checkbox"/> M <input type="checkbox"/> N <input type="checkbox"/></p>

<p>treatment of malnutrition in pediatric hemodialysis patients. <i>Pediatric Nephrology</i> (2002) 17:531-534).</p> <p>3a.5 Methods (e.g., focus group, survey, QI project): N/A</p> <p>3a.6 Results (qualitative and/or quantitative results and conclusions): N/A</p>	
<p>3b/3c. Relation to other NQF-endorsed measures</p> <p>3b.1 NQF # and Title of similar or related measures:</p>	
<p>(for NQF staff use) Notes on similar/related endorsed or submitted measures:</p>	
<p>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 <u>or</u> different topic but same target population):</p> <p>3b.2 Are the measure specifications harmonized? If not, why?</p>	<p>3b C <input type="checkbox"/> P <input type="checkbox"/> M <input type="checkbox"/> N <input type="checkbox"/> NA <input type="checkbox"/></p>
<p>3c. Distinctive or Additive Value</p> <p>3c.1 Describe the distinctive, improved, or additive value this measure provides to existing NQF-endorsed measures:</p> <p>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: N/A</p>	<p>3c C <input type="checkbox"/> P <input type="checkbox"/> M <input type="checkbox"/> N <input type="checkbox"/> NA <input type="checkbox"/></p>
<p>TAP/Workgroup: What are the strengths and weaknesses in relation to the subcriteria for <i>Usability</i>?</p>	<p>3</p>
<p>Steering Committee: Overall, to what extent was the criterion, <i>Usability</i>, met? Rationale:</p>	<p>3 C <input type="checkbox"/> P <input type="checkbox"/> M <input type="checkbox"/> N <input type="checkbox"/></p>
4. FEASIBILITY	
<p>Extent to which the required data are readily available, retrievable without undue burden, and can be implemented for performance measurement. (evaluation criteria)</p>	<p>Eval Rating</p>
<p>4a. Data Generated as a Byproduct of Care Processes</p> <p>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)</p>	<p>4a C <input type="checkbox"/> P <input type="checkbox"/> M <input type="checkbox"/> N <input type="checkbox"/></p>
<p>4b. Electronic Sources</p> <p>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</p> <p>4b.2 If not, specify the near-term path to achieve electronic capture by most providers.</p>	<p>4b C <input type="checkbox"/> P <input type="checkbox"/> M <input type="checkbox"/> N <input type="checkbox"/></p>
<p>4c. Exclusions</p> <p>4c.1 Do the specified exclusions require additional data sources beyond what is required for the numerator and denominator specifications?</p>	<p>4c C <input type="checkbox"/> P <input type="checkbox"/> M <input type="checkbox"/></p>

<p>No</p> <p>4c.2 If yes, provide justification.</p>	<p>N <input type="checkbox"/></p> <p>NA <input type="checkbox"/></p>
<p>4d. Susceptibility to Inaccuracies, Errors, or Unintended Consequences</p> <p>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 used are similar to the calculation of another measure. Similar to that measure (calculation of spKt/V), these data and the measure are not susceptible to inaccuracies, errors or unintended consequences.</p>	<p>4d</p> <p>C <input type="checkbox"/></p> <p>P <input type="checkbox"/></p> <p>M <input type="checkbox"/></p> <p>N <input type="checkbox"/></p>
<p>4e. Data Collection Strategy/Implementation</p> <p>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.</p> <p>4e.2 Costs to implement the measure (<i>costs of data collection, fees associated with proprietary measures</i>): 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</p> <p>4e.3 Evidence for costs: See above reference to Federal Register.</p> <p>4e.4 Business case documentation: No formal cost-effectiveness analyses have been performed evaluating the benefits of regular nPCR measurements. However, nPCR provides an estimate of dietary protein intake. In malnourished adolescent patients who achieved target spKt/V levels, nPCR, but not serum albumin, was associated with nutritional status [1, 2]. In adolescent patients, nPCR levels < 1 gram/kg/day were found to be an earlier and more sensitive marker than serum albumin levels in predicting malnutrition and sustained weight loss [3]. Since malnutrition is associated with increased risk of hospitalization, improving nutritional status may potentially be associated with reduced hospitalization rates and associated cost-savings.</p> <p>1. Goldstein, Baronette, et al. nPCR assessment and IDPN treatment of malnutrition in pediatric hemodialysis patients. <i>Pediatric Nephrology</i> (2002) 17:531-534. 2. Orellana P, Juarez-Congelosi M, Goldstein SL. Intradialytic parenteral nutrition treatment and biochemical marker assessment for malnutrition in adolescent maintenance hemodialysis patients. <i>J Ren Nutrition</i> 2005 Jul;15(3):312-7. 3. Juarez-Congelosi M, Orellana P, Goldstein SL: Normalized protein catabolic rate versus serum albumin as a nutrition status marker in pediatric patients receiving hemodialysis. <i>J Ren Nutr</i> 17:269-274, 2007.</p>	<p>4e</p> <p>C <input type="checkbox"/></p> <p>P <input type="checkbox"/></p> <p>M <input type="checkbox"/></p> <p>N <input type="checkbox"/></p>
<p>TAP/Workgroup: What are the strengths and weaknesses in relation to the subcriteria for <i>Feasibility</i>?</p>	<p>4</p>
<p>Steering Committee: Overall, to what extent was the criterion, <i>Feasibility</i>, met? Rationale:</p>	<p>4</p> <p>C <input type="checkbox"/></p> <p>P <input type="checkbox"/></p> <p>M <input type="checkbox"/></p> <p>N <input type="checkbox"/></p>
<p>RECOMMENDATION</p>	
<p>(for NQF staff use) Check if measure is untested and only eligible for time-limited endorsement.</p>	<p>Time-limited <input type="checkbox"/></p>

Steering Committee: Do you recommend for endorsement? Comments:	Y <input type="checkbox"/> N <input type="checkbox"/> A <input type="checkbox"/>
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, 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? 3 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	