

# 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 #: 1418	NQF Project: End Stage Renal Disease
MEASURE DESCRIPTIVE INFORMATION	
De.1 Measure Title: <a href="#">Frequency of Adequacy Measurement for Pediatric Hemodialysis Patients</a>	
De.2 Brief description of measure: <a href="#">Percentage of all pediatric (&lt;18 years) patients receiving in-center hemodialysis (irrespective of frequency of dialysis) with documented monthly adequacy measurements (spKt/V) or its components in the calendar month</a>	
1.1-2 Type of Measure: <a href="#">Process</a>	
De.3 If included in a composite or paired with another measure, please identify composite or paired measure <a href="#">Method of Adequacy Measurement for Pediatric Hemodialysis Patients</a> <a href="#">Minimum spKt/V for Pediatric Hemodialysis Patients</a>	
De.4 National Priority Partners Priority Area: <a href="#">Population health</a>	
De.5 IOM Quality Domain: <a href="#">Effectiveness</a>	
De.6 Consumer Care Need: <a href="#">Living with illness</a>	

CONDITIONS FOR CONSIDERATION BY NQF	
Four conditions must be met before proposed measures may be considered and evaluated for suitability as voluntary consensus standards:	<b>NQF Staff</b>
<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)? <a href="#">Yes</a></p> <p>A.2 Indicate if Proprietary Measure (as defined in measure steward agreement):</p> <p>A.3 Measure Steward Agreement: <a href="#">Government entity and in the public domain - no agreement necessary</a></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 every 3 years. <a href="#">Yes, information provided in contact section</a>	B Y <input type="checkbox"/> N <input type="checkbox"/>
C. The intended use of the measure includes <u>both</u> public reporting <u>and</u> quality improvement. ► <b>Purpose:</b> <a href="#">Public reporting</a> , <a href="#">Internal quality improvement</a>	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: <a href="#">Yes, fully developed and tested</a> D.2 Have NQF-endorsed measures been reviewed to identify if there are similar or related measures? <a href="#">Yes</a>	D Y <input type="checkbox"/> N <input type="checkbox"/>
<b>(for NQF staff use)</b> 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:	
<b>1. IMPORTANCE TO MEASURE AND REPORT</b>	
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
<b>(for NQF staff use)</b> Specific NPP goal:	
1a.1 Demonstrated High Impact Aspect of Healthcare: <a href="#">Frequently performed procedure, Severity of illness</a> 1a.2 1a.3 Summary of Evidence of High Impact: <a href="#">The incidence and prevalence rates of pediatric end-stage renal disease (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].</a>	1a C <input type="checkbox"/> P <input type="checkbox"/> M <input type="checkbox"/> N <input type="checkbox"/>
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	

**Comment [KP1]:** 1a. The measure focus addresses:  
 • a specific national health goal/priority identified by NQF's National Priorities Partners; OR  
 • a demonstrated high impact aspect of healthcare (e.g., affects large numbers, leading cause of morbidity/mortality, high resource use (current and/or future), severity of illness, and patient/societal consequences of poor quality).

<p>improved growth with intensive hemodialysis regimens [6,7].</p> <p>Prior studies have used a monthly interval of measurement of hemodialysis dose [3,4]. Furthermore, 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. Currently there is variation in the frequency of measurement of hemodialysis adequacy among the pediatric population. Analysis of 2007 Clinical Performance Measures (CPM) data demonstrate that during the 3 month study period, dialysis adequacy using spKt/V was not measured at any time in 20% of pediatric patients. For all of these reasons, monthly measurement of HD adequacy is a highly important measure in the pediatric population.</p> <p><b>1a.4 Citations for Evidence of High Impact:</b></p> <ol style="list-style-type: none"> <li>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.</li> <li>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.</li> <li>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.</li> <li>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.</li> <li>5. Gorman G, et al. Clinical outcomes and dialysis adequacy in adolescent hemodialysis patients. Am Journal Kidney Dis; 47: 285-93, 2006.</li> <li>6. Fischbach M, et al. Intensified and daily hemodialysis in children might improve statural growth. Pediatr Nephrol 21:1746-1752, 2006.</li> <li>7. Tom A, et al. Growth during maintenance hemodialysis: impact of enhanced nutrition and clearance. J Pediatr. Apr;134(4):464-71, 1999.</li> </ol>	
<p><b>1b. Opportunity for Improvement</b></p> <p><b>1b.1 Benefits (improvements in quality) envisioned by use of this measure:</b> By requiring a minimum of monthly evaluation of HD adequacy, timely dose adjustments can be made, which is critical among pediatric patients in a growth phase. Small scale observational studies support the association between delivered hemodialysis dose and patient outcomes including the potential for improved growth with intensive hemodialysis regimens.</p> <p><b>1b.2 Summary of data demonstrating performance gap (variation or overall poor performance) across providers:</b> Currently there is variation in the frequency of measurement of hemodialysis adequacy among the pediatric population. CPM data demonstrate that over 20% of pediatric patients do not have documented Kt/V values. Also, there are many pediatric patients who are dialyzed in adult hemodialysis facilities, and therefore, may not be monitored.</p> <p><b>1b.3 Citations for data on performance gap:</b> Internal analysis of CPM data.</p> <p><b>1b.4 Summary of Data on disparities by population group:</b> 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 (<math>\beta=0.13</math>, <math>p&lt;0.05</math>) and among Nonblack patients compared to Black patients (<math>\beta=0.22</math>, <math>p&lt;0.001</math>).</p> <p><b>1b.5 Citations for data on Disparities:</b> Leonard MB, et al. Racial and center differences in hemodialysis adequacy in children treated at pediatric</p>	<p><b>1b</b> C <input type="checkbox"/> P <input type="checkbox"/> M <input type="checkbox"/> N <input type="checkbox"/></p>

**Comment [KP2]:** 1b. Demonstration of quality problems and opportunity for improvement, i.e., data demonstrating considerable variation, or overall poor performance, in the quality of care across providers and/or population groups (disparities in care).

**Comment [k3]:** 1 Examples of data on opportunity for improvement include, but are not limited to: prior studies, epidemiologic data, measure data from pilot testing or implementation. If data are not available, the measure focus is systematically assessed (e.g., expert panel rating) and judged to be a quality problem.

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 should be used for month-to-month assessment of hemodialysis dose [6]. Although large scale clinical trials have not been conducted in the pediatric hemodialysis population, smaller scale observational studies support the association between delivered hemodialysis dose and patient outcomes [3] including the potential for improved growth with intensive hemodialysis regimens [4,5].

**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:** There is no controversial or contradictory evidence for this measure.

**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.

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. Clinical Practice Guidelines for Hemodialysis Adequacy: KDOQI Guideline 8. Pediatric Hemodialysis Prescription and Adequacy: 2006.

**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  
C   
P   
M   
N

**Comment [k4]:** 1c. The measure focus is:  
•an outcome (e.g., morbidity, mortality, function, health-related quality of life) that is relevant to, or associated with, a national health goal/priority, the condition, population, and/or care being addressed;  
OR

•if an intermediate outcome, process, structure, etc., there is evidence that supports the specific measure focus as follows:  
oIntermediate outcome - evidence that the measured intermediate outcome (e.g., blood pressure, Hba1c) leads to improved health/avoidance of harm or cost/benefit  
oProcess - evidence that the measured clinical or administrative process leads to improved health/avoidance of harm and  
if the measure focus is on one step in a multi-step care process, it measures the step that has the greatest effect on improving the specified desired outcome(s).

oStructure - evidence that the measured structure supports the consistent delivery of effective processes or access that lead to improved health/avoidance of harm or cost/benefit.

oPatient experience - evidence that an association exists between the measure of patient experience of health care and the outcomes, values and preferences of individuals/ the public.

oAccess - evidence that an association exists between access to a health service and the outcomes of, or experience with, care. ... [1]

**Comment [k5]:** 4 Clinical care processes typically include multiple steps: assess → identify problem/potential problem → choose/plan intervention (with patient input) → provide intervention → evaluate impact on health status. If the measure focus is one step in such a multi-step process, the step with the greatest effect on the desired outcome should be selected as the focus of measurement. For example, although assessment of immunization status and recommending immunization are necessary steps, they are not sufficient to achieve the desired impact on health status - patients must be vaccinated to achieve immunity. This does not preclude consideration of measures of preventive screening interventions where there is a strong link with desired outcomes (e.g., mammography) or measures for multiple care processes that affect a single outcome.

**Comment [k6]:** 3 The strength of the body of evidence for the specific measure focus should be systematically assessed and rated (e.g., USPSTF grading system <http://www.ahrq.gov/clinic/uspstf07/methods/benefit.htm>). If the USPSTF grading system was not used, the grading system is explained including how it relates to the USPSTF grades or why it does not. However, evidence is not limited to quantitative studies and the best type of evidence depends upon the question being studied (e.g., randomized controlled trials appropriate for studying drug efficacy are not well suited for complex system changes). When qualitative studies are used, appropriate qualitative research criteria are used to judge the strength of the evidence.

<p><b>1c.12 Rating of strength of recommendation</b> <i>(also provide narrative description of the rating and by whom):</i>                  CPG 8.2.1 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><b>1c.13 Method for rating strength of recommendation</b> <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 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.</p> <p><b>1c.14 Rationale for using this guideline over others:</b>                  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 frequency of measurement of hemodialysis adequacy.</p>	
<p><b>TAP/Workgroup: What are the strengths and weaknesses in relation to the subcriteria for Importance to Measure and Report?</b></p>	<p>1</p>
<p><b>Steering Committee: Was the threshold criterion, Importance to Measure and Report, met? Rationale:</b></p>	<p>1                  Y <input type="checkbox"/>                  N <input type="checkbox"/></p>
<p style="text-align: center;"><b>2. SCIENTIFIC ACCEPTABILITY OF MEASURE PROPERTIES</b></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 style="text-align: center;"><b>2a. MEASURE SPECIFICATIONS</b></p>	
<p><b>S.1 Do you have a web page where current detailed measure specifications can be obtained?</b>  <b>S.2 If yes, provide web page URL:</b></p> <p><b>2a. Precisely Specified</b></p>	
<p><b>2a.1 Numerator Statement</b> <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 adequacy measurements (spKt/V) or its components in the calendar month.</p> <p><b>2a.2 Numerator Time Window</b> <i>(The time period in which cases are eligible for inclusion in the numerator):</i>                  The entire calendar month</p> <p><b>2a.3 Numerator Details</b> <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 in the one month study period: "Kt/V Hemodialysis Collection Date" is populated, AND "Kt/V Hemodialysis" 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.</p>	<p><b>2a-specs</b>                  C <input type="checkbox"/>                  P <input type="checkbox"/>                  M <input type="checkbox"/>                  N <input type="checkbox"/></p>

**Comment [k7]:** USPSTF grading system <http://www.ahrq.gov/clinic/uspstf/grades.htm>: A - The USPSTF recommends the service. There is high certainty that the net benefit is substantial. B - The USPSTF recommends the service. There is high certainty that the net benefit is moderate or there is moderate certainty that the net benefit is moderate to substantial. C - The USPSTF recommends against routinely providing the service. There may be considerations that support providing the service in an individual patient. There is at least moderate certainty that the net benefit is small. Offer or provide this service only if other considerations support the offering or providing the service in an individual patient. D - The USPSTF recommends against the service. There is moderate or high certainty that the service has no net benefit or that the harms outweigh the benefits. I - The USPSTF concludes that the current evidence is insufficient to assess the balance of benefits and harms of the service. Evidence is lacking, of poor quality, or conflicting, and the balance of benefits and harms cannot be determined.

**Comment [KP8]:** 2a. The measure is well defined and precisely specified so that it can be implemented consistently within and across organizations and allow for comparability. The required data elements are of high quality as defined by NQF's Health Information Technology Expert Panel (HITEP).

<p><b>2a.4 Denominator Statement</b> (<i>Brief, text description of the denominator - target population being measured</i>):                  Number of pediatric patients (&lt;18 years) receiving in-center hemodialysis (irrespective of frequency of dialysis) who are in the facility and on hemodialysis for the entire study period.</p>
<p><b>2a.5 Target population gender:</b> Female, Male  <b>2a.6 Target population age range:</b> Pediatric patients less than 18 years old</p>
<p><b>2a.7 Denominator Time Window</b> (<i>The time period in which cases are eligible for inclusion in the denominator</i>):                  The entire calendar month.</p>
<p><b>2a.8 Denominator Details</b> (<i>All information required to collect/calculate the denominator - the target population being measured - including all codes, logic, and definitions</i>):                  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 &lt;18 years old who are determined to be in-center hemodialysis patients.</p>
<p><b>2a.9 Denominator Exclusions</b> (<i>Brief text description of exclusions from the target population</i>): Patients on home dialysis, patients not in the facility for the entire calendar month.</p>
<p><b>2a.10 Denominator Exclusion Details</b> (<i>All information required to collect exclusions to the denominator, including all codes, logic, and definitions</i>):                  See denominator details.</p>
<p><b>2a.11 Stratification Details/Variables</b> (<i>All information required to stratify the measure including the stratification variables, all codes, logic, and definitions</i>):                  No stratification is required for this measure.</p>
<p><b>2a.12-13 Risk Adjustment Type:</b> No risk adjustment necessary</p>
<p><b>2a.14 Risk Adjustment Methodology/Variables</b> (<i>List risk adjustment variables and describe conceptual models, statistical models, or other aspects of model or method</i>):                  N/A</p>
<p><b>2a.15-17 Detailed risk model available Web page URL or attachment:</b></p>
<p><b>2a.18-19 Type of Score:</b> Rate/proportion  <b>2a.20 Interpretation of Score:</b> Better quality = Higher score  <b>2a.21 Calculation Algorithm</b> (<i>Describe the calculation of the measure as a flowchart or series of steps</i>):                  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 &lt;18 years old who are determined to be in-center hemodialysis patients.                  The numerator will be determined by counting the patients in the denominator who meet one of the following criteria in the one month study period: "Kt/V Hemodialysis Collection Date" is populated, AND "Kt/V Hemodialysis" 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-</p>

**Comment [k9]:** 11 Risk factors that influence outcomes should not be specified as exclusions.  
 12 Patient preference is not a clinical exception to eligibility and can be influenced by provider interventions.

Dialysis Weight Unit of Measure" is populated, AND "Delivered Minutes of BUN Hemodialysis Session" is populated.	
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 clinical data	
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 <a href="http://www.projectcrownweb.org/crown/index.php">http://www.projectcrownweb.org/crown/index.php</a>	
2a.29-31 Data dictionary/code table web page URL or attachment:	
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	
<b>TESTING/ANALYSIS</b>	
2b. Reliability testing	
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): For weekly Kt/V>=1.2, the average Kappa statistic (of October, November, and December) for missing vs. non-missing values ranged from 0.94 to 0.96. The average level of concurrence (LOC) for missing vs. non-missing was 92%. Generally, acceptable agreement rates are 0.80 or higher and concurrence targets are 90% or higher.	2b C <input type="checkbox"/> P <input type="checkbox"/> M <input type="checkbox"/> N <input type="checkbox"/>
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 C <input type="checkbox"/> P <input type="checkbox"/> M <input type="checkbox"/> N <input type="checkbox"/>

**Comment [KP10]:** 2b. Reliability testing demonstrates the measure results are repeatable, producing the same results a high proportion of the time when assessed in the same population in the same time period.

**Comment [k11]:** 8 Examples of reliability testing include, but are not limited to: inter-rater/abstractor or intra-rater/abstractor studies; internal consistency for multi-item scales; test-retest for survey items. Reliability testing may address the data items or final measure score.

**Comment [KP12]:** 2c. Validity testing demonstrates that the measure reflects the quality of care provided, adequately distinguishing good and poor quality. If face validity is the only validity addressed, it is systematically assessed.

<p><b>2c.2 Analytic Method</b> (<i>type of validity &amp; rationale, method for testing</i>): Face validity is the only validity assessed, as there is no gold standard for defining the ideal frequency of measuring hemodialysis adequacy in the pediatric population.</p> <p><b>2c.3 Testing Results</b> (<i>statistical results, assessment of adequacy in the context of norms for the test conducted</i>): N/A</p>	
<p><b>2d. Exclusions Justified</b></p> <p><b>2d.1 Summary of Evidence supporting exclusion(s)</b>: Exclusions are not supported by evidence. However, they are limited to those with a compelling clinical rationale and are precisely defined.</p> <p><b>2d.2 Citations for Evidence</b>: N/A</p> <p><b>2d.3 Data/sample</b> (<i>description of data/sample and size</i>): N/A</p> <p><b>2d.4 Analytic Method</b> (<i>type analysis &amp; rationale</i>): N/A</p> <p><b>2d.5 Testing Results</b> (<i>e.g., frequency, variability, sensitivity analyses</i>): N/A</p>	<p>2d C <input type="checkbox"/> P <input type="checkbox"/> M <input type="checkbox"/> N <input type="checkbox"/> NA <input type="checkbox"/></p>
<p><b>2e. Risk Adjustment for Outcomes/ Resource Use Measures</b></p> <p><b>2e.1 Data/sample</b> (<i>description of data/sample and size</i>): No risk adjustments are necessary for this measure.</p> <p><b>2e.2 Analytic Method</b> (<i>type of risk adjustment, analysis, &amp; rationale</i>): N/A</p> <p><b>2e.3 Testing Results</b> (<i>risk model performance metrics</i>): N/A</p> <p><b>2e.4 If outcome or resource use measure is not risk adjusted, provide rationale</b>: N/A</p>	<p>2e C <input type="checkbox"/> P <input type="checkbox"/> M <input type="checkbox"/> N <input type="checkbox"/> NA <input type="checkbox"/></p>
<p><b>2f. Identification of Meaningful Differences in Performance</b></p> <p><b>2f.1 Data/sample from Testing or Current Use</b> (<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><b>2f.2 Methods to identify statistically significant and practically/meaningfully differences in performance</b> (<i>type of analysis &amp; rationale</i>): Facility level performance was evaluated using descriptive statistics including facility level means and percentages.</p> <p><b>2f.3 Provide Measure Scores from Testing or Current Use</b> (<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.</p>	<p>2f C <input type="checkbox"/> P <input type="checkbox"/> M <input type="checkbox"/> N <input type="checkbox"/></p>
<p><b>2g. Comparability of Multiple Data Sources/Methods</b></p>	<p>2g C <input type="checkbox"/></p>

**Comment [k13]:** 9 Examples of validity testing include, but are not limited to: determining if measure scores adequately distinguish between providers known to have good or poor quality assessed by another valid method; correlation of measure scores with another valid indicator of quality for the specific topic; ability of measure scores to predict scores on some other related valid measure; content validity for multi-item scales/tests. Face validity is a subjective assessment by experts of whether the measure reflects the quality of care (e.g., whether the proportion of patients with BP < 140/90 is a marker of quality). If face validity is the only validity addressed, it is systematically assessed (e.g., ratings by relevant stakeholders) and the measure is judged to represent quality care for the specific topic and that the measure focus is the most important aspect of quality for the specific topic.

**Comment [KP14]:** 2d. Clinically necessary measure exclusions are identified and must be: supported by evidence of sufficient frequency of occurrence so that results are distorted without the exclusion; AND a clinically appropriate exception (e.g., contraindication) to eligibility for the measure focus; ... [2]

**Comment [k15]:** 10 Examples of evidence that an exclusion distorts measure results include, but are not limited to: frequency of occurrence, sensitivity analyses with and without the exclusion, and variability of exclusions across providers.

**Comment [KP16]:** 2e. For outcome measures and other measures (e.g., resource use) when indicated: an evidence-based risk-adjustment strategy (e.g., risk models, risk stratification) is specified and is based on patient clinical factors that influence the measured outcome; ... [3]

**Comment [k17]:** 13 Risk models should not obscure disparities in care for populations by including factors that are associated with differences/inequalities in care such as race, socioeconomic status, gender (e.g., poorer treatment outcomes of African American men with prostate cancer, inequalities in treatment for CVD risk factors between men and women); ... [4]

**Comment [KP18]:** 2f. Data analysis demonstrates that methods for scoring and analysis of the specified measure allow for identification of statistically significant and practically/clinically meaningful differences in performance.

**Comment [k19]:** 14 With large enough sample sizes, small differences that are statistically significant may or may not be practically or clinically meaningful. The substantive question may be, for example, whether a statistically significant difference of one percentage point in the percentage of patients who received smoking cessation; ... [5]

**Comment [KP20]:** 2g. If multiple data sources/methods are allowed, there is demonstration they produce comparable results.

<p><b>2g.1 Data/sample</b> (<i>description of data/sample and size</i>): 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><b>2g.2 Analytic Method</b> (<i>type of analysis &amp; rationale</i>): Multiple data sources are not allowed for this measure, and therefore testing is not needed.</p> <p><b>2g.3 Testing Results</b> (<i>e.g., correlation statistics, comparison of rankings</i>): N/A</p>	<p>P <input type="checkbox"/> M <input type="checkbox"/> N <input type="checkbox"/> NA <input type="checkbox"/></p>
<p><b>2h. Disparities in Care</b></p> <p><b>2h.1</b> If measure is stratified, provide stratified results (<i>scores by stratified categories/cohorts</i>): N/A</p> <p><b>2h.2</b> 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><b>TAP/Workgroup:</b> What are the strengths and weaknesses in relation to the subcriteria for <i>Scientific Acceptability of Measure Properties</i>?</p>	<p>2</p>
<p><b>Steering Committee:</b> 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>
<p><b>3. USABILITY</b></p>	
<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><b>3a. Meaningful, Understandable, and Useful Information</b></p> <p><b>3a.1 Current Use:</b> Not in use but testing completed</p> <p><b>3a.2 Use in a public reporting initiative</b> (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>): The 2008 ESRD Clinical Performance Measures Project presents data on the adult and pediatric ESRD population. URL: <a href="http://www.cms.hhs.gov/CPMProject">www.cms.hhs.gov/CPMProject</a>.</p> <p><b>3a.3 If used in other programs/initiatives</b> (<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>): 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.</p> <p><b>Testing of Interpretability</b> (<i>Testing that demonstrates the results are understood by the potential users for public reporting and quality improvement</i>)</p> <p><b>3a.4 Data/sample</b> (<i>description of data/sample and size</i>): Testing of interpretability has not been performed.</p> <p><b>3a.5 Methods</b> (<i>e.g., focus group, survey, QI project</i>): N/A</p>	<p>3a C <input type="checkbox"/> P <input type="checkbox"/> M <input type="checkbox"/> N <input type="checkbox"/></p>

**Comment [KP21]:** 2h. If disparities in care have been identified, measure specifications, scoring, and analysis allow for identification of disparities through stratification of results (e.g., by race, ethnicity, socioeconomic status, gender); OR rationale/data justifies why stratification is not necessary or not feasible.

**Comment [KP22]:** 3a. Demonstration that information produced by the measure is meaningful, understandable, and useful to the intended audience(s) for both public reporting (e.g., focus group, cognitive testing) and informing quality improvement (e.g., quality improvement initiatives). An important outcome that may not have an identified improvement strategy still can be useful for informing quality improvement by identifying the need for and stimulating new approaches to improvement.

3a.6 Results (qualitative and/or quantitative results and conclusions): N/A	
3b/3c. Relation to other NQF-endorsed measures	
3b.1 NQF # and Title of similar or related measures: NQF # 0247. ESRD- HD Adequacy CPM I: Monthly measurement of delivered dialysis 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 listed above.	3b C <input type="checkbox"/> P <input type="checkbox"/> M <input type="checkbox"/> N <input type="checkbox"/> NA <input type="checkbox"/>
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 <input type="checkbox"/> P <input type="checkbox"/> M <input type="checkbox"/> N <input type="checkbox"/> NA <input type="checkbox"/>
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 <input type="checkbox"/> P <input type="checkbox"/> M <input type="checkbox"/> N <input type="checkbox"/>
<b>4. FEASIBILITY</b>	
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 <input type="checkbox"/> P <input type="checkbox"/> M <input type="checkbox"/> N <input type="checkbox"/>
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 <input type="checkbox"/> P <input type="checkbox"/> M <input type="checkbox"/> N <input type="checkbox"/>
4c. Exclusions 4c.1 Do the specified exclusions require additional data sources beyond what is required for the numerator and denominator specifications? No	4c C <input type="checkbox"/> P <input type="checkbox"/> M <input type="checkbox"/> N <input type="checkbox"/> NA <input type="checkbox"/>

**Comment [KP23]:** 3b. The measure specifications are harmonized with other measures, and are applicable to multiple levels and settings.

**Comment [k24]:** 16 Measure harmonization refers to the standardization of specifications for similar measures on the same topic (e.g., influenza immunization of patients in hospitals or nursing homes), or related measures for the same target population (e.g., eye exam and HbA1c for patients with diabetes), or definitions applicable to many measures (e.g., age designation for children) so that they are uniform or compatible, unless differences are dictated by the evidence. The dimensions of harmonization can include numerator, denominator, exclusions, and data source and collection instructions. The extent of harmonization depends on the relationship of the measures, the evidence for the specific measure focus, and differences in data sources.

**Comment [KP25]:** 3c. Review of existing endorsed measures and measure sets demonstrates that the measure provides a distinctive or additive value to existing NQF-endorsed measures (e.g., provides a more complete picture of quality for a particular condition or aspect of healthcare, is a more valid or efficient way to measure).

**Comment [KP26]:** 4a. For clinical measures, required data elements are routinely generated concurrent with and as a byproduct of care processes during care delivery. (e.g., BP recorded in the electronic record, not abstracted from the record later by other personnel; patient self-assessment tools, e.g., depression scale; lab values, meds, etc.)

**Comment [KP27]:** 4b. The required data elements are available in electronic sources. If the required data are not in existing electronic sources, a credible, near-term path to electronic collection by most providers is specified and clinical data elements are specified for transition to the electronic health record.

**Comment [KP28]:** 4c. Exclusions should not require additional data sources beyond what is required for scoring the measure (e.g., numerator and denominator) unless justified as supporting measure validity.

4c.2 If yes, provide justification.	
4d. Susceptibility to Inaccuracies, Errors, or Unintended Consequences	
<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 elements for this measure are already being collected and are unlikely to be susceptible to inaccuracies, errors or unintended consequences.</p>	4d C <input type="checkbox"/> P <input type="checkbox"/> M <input type="checkbox"/> N <input type="checkbox"/>
4e. Data Collection Strategy/Implementation	
<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: <a href="http://www.cms.gov/CFCsAndCoPs/downloads/ESRDfinalrule0415.pdf">http://www.cms.gov/CFCsAndCoPs/downloads/ESRDfinalrule0415.pdf</a></p> <p>4e.3 Evidence for costs:                  See above reference to Federal Register.</p> <p>4e.4 Business case documentation: 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 with increased cost, efforts to reduce hospitalization, including improving adequacy of hemodialysis treatments may potentially result in cost-savings.</p> <p>1. Gorman G, et al. Clinical outcomes and dialysis adequacy in adolescent hemodialysis patients. <i>Am Journal Kidney Dis</i>; 47: 285-93, 2006.</p>	4e C <input type="checkbox"/> P <input type="checkbox"/> M <input type="checkbox"/> N <input type="checkbox"/>
TAP/Workgroup: What are the strengths and weaknesses in relation to the subcriteria for <i>Feasibility</i> ?	4
Steering Committee: Overall, to what extent was the criterion, <i>Feasibility</i> , met? Rationale:	4 C <input type="checkbox"/> P <input type="checkbox"/> M <input type="checkbox"/> N <input type="checkbox"/>
<b>RECOMMENDATION</b>	
(for NQF staff use) Check if measure is untested and only eligible for time-limited endorsement.	Time-limited <input type="checkbox"/>
Steering Committee: Do you recommend for endorsement? Comments:	Y <input type="checkbox"/> N <input type="checkbox"/> A <input type="checkbox"/>
<b>CONTACT INFORMATION</b>	
Co.1 Measure Steward (Intellectual Property Owner) Co.1 <u>Organization</u> Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, Maryland, 21244	

**Comment [KP29]:** 4d. Susceptibility to inaccuracies, errors, or unintended consequences and the ability to audit the data items to detect such problems are identified.

**Comment [KP30]:** 4e. Demonstration that the data collection strategy (e.g., source, timing, frequency, sampling, patient confidentiality, etc.) can be implemented (e.g., already in operational use, or testing demonstrates that it is ready to put into operational use).

<p><b>Co.2 Point of Contact</b>                  Thomas, Dudley, <a href="mailto:Thomas.Dudley@cms.hhs.gov">Thomas.Dudley@cms.hhs.gov</a>, 410-786-1442-</p>
<p>Measure Developer If different from Measure Steward  <b>Co.3 Organization</b>                  Arbor Research/UM-KECC, 315 W. Huron, Suite 360, Ann Arbor, Michigan, 48103</p>
<p><b>Co.4 Point of Contact</b>                  Adrienne, Janney, <a href="mailto:adrienne.janney@arborresearch.org">adrienne.janney@arborresearch.org</a>, 734-665-4108-</p>
<p><b>Co.5 Submitter If different from Measure Steward POC</b>                  Thomas, Dudley, <a href="mailto:Thomas.Dudley@cms.hhs.gov">Thomas.Dudley@cms.hhs.gov</a>, 410-786-1442-, Centers for Medicare &amp; Medicaid Services</p>
<p><b>Co.6 Additional organizations that sponsored/participated in measure development</b></p>
<p><b>ADDITIONAL INFORMATION</b></p>
<p><b>Workgroup/Expert Panel involved in measure development</b>                  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)</p>
<p><b>Ad.2 If adapted, provide name of original measure:</b>                  Ad.3-5 If adapted, provide original specifications URL or attachment</p>
<p>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? <a href="#">Three years</a>                  Ad.9 When is the next scheduled review/update for this measure? <a href="#">2013</a></p>
<p><b>Ad.10 Copyright statement/disclaimers:</b></p>
<p><b>Ad.11 -13 Additional Information web page URL or attachment:</b></p>
<p><b>Date of Submission (MM/DD/YY):</b> <a href="#">09/28/2010</a></p>

**Page 4: [1] Comment [k4]** **Karen Pace** **10/5/2009 8:59:00 AM**

1c. The measure focus is:

- an outcome (e.g., morbidity, mortality, function, health-related quality of life) that is relevant to, or associated with, a national health goal/priority, the condition, population, and/or care being addressed;

OR

- if an intermediate outcome, process, structure, etc., there is evidence that supports the specific measure focus as follows:
  - o Intermediate outcome - evidence that the measured intermediate outcome (e.g., blood pressure, Hba1c) leads to improved health/avoidance of harm or cost/benefit.
  - o Process - evidence that the measured clinical or administrative process leads to improved health/avoidance of harm and  
if the measure focus is on one step in a multi-step care process, it measures the step that has the greatest effect on improving the specified desired outcome(s).
  - o Structure - evidence that the measured structure supports the consistent delivery of effective processes or access that lead to improved health/avoidance of harm or cost/benefit.
  - o Patient experience - evidence that an association exists between the measure of patient experience of health care and the outcomes, values and preferences of individuals/ the public.
  - o Access - evidence that an association exists between access to a health service and the outcomes of, or experience with, care.
  - o Efficiency - demonstration of an association between the measured resource use and level of performance with respect to one or more of the other five IOM aims of quality.

**Page 8: [2] Comment [KP14]** **Karen Pace** **10/5/2009 8:59:00 AM**

2d. Clinically necessary measure exclusions are identified and must be:

- supported by evidence of sufficient frequency of occurrence so that results are distorted without the exclusion;
- AND

- a clinically appropriate exception (e.g., contraindication) to eligibility for the measure focus;
- AND

- precisely defined and specified:

- if there is substantial variability in exclusions across providers, the measure is specified so that exclusions are computable and the effect on the measure is transparent (i.e., impact clearly delineated, such as number of cases excluded, exclusion rates by type of exclusion);

if patient preference (e.g., informed decision-making) is a basis for exclusion, there must be evidence that it strongly impacts performance on the measure and the measure must be specified so that the information about patient preference and the effect on the measure is transparent (e.g., numerator category computed separately, denominator exclusion category computed separately).

**Page 8: [3] Comment [KP16]** **Karen Pace** **10/5/2009 8:59:00 AM**

2e. For outcome measures and other measures (e.g., resource use) when indicated:

- an evidence-based risk-adjustment strategy (e.g., risk models, risk stratification) is specified and is based on patient clinical factors that influence the measured outcome (but not disparities in care) and are present at start of care;  
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rationale/data support no risk adjustment.

**Page 8: [4] Comment [k17]** **Karen Pace** **10/5/2009 8:59:00 AM**

13 Risk models should not obscure disparities in care for populations by including factors that are associated with differences/inequalities in care such as race, socioeconomic status, gender (e.g., poorer treatment outcomes of African American men with prostate cancer, inequalities in treatment for CVD risk factors between men and women). It is preferable to stratify measures by race and socioeconomic status rather than adjusting out differences.

**Page 8: [5] Comment [k19]** **Karen Pace** **10/5/2009 8:59:00 AM**

14 With large enough sample sizes, small differences that are statistically significant may or may not be practically or clinically meaningful. The substantive question may be, for example, whether a statistically significant difference of one percentage point in the percentage of patients who received smoking cessation counseling (e.g., 74% v. 75%) is clinically meaningful; or whether a statistically significant difference of \$25 in cost for an episode of care (e.g., \$5,000 v. \$5,025) is practically meaningful. Measures with overall poor performance may not