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)
B. The measure owner/steward verifies there is an identified responsible entity and process to maintain and update the measure on a schedule that is commensurate with the rate of clinical innovation, but at least every 3 years. Yes, information provided in contact section

C. The intended use of the measure includes both public reporting and quality improvement.
   ▶ Purpose: Public reporting, Internal quality improvement

D. The requested measure submission information is complete. Generally, measures should be fully developed and tested so that all the evaluation criteria have been addressed and information needed to evaluate the measure is provided. Measures that have not been tested are only potentially eligible for a time-limited endorsement and in that case, measure owners must verify that testing will be completed within 12 months of endorsement.

D.1 Testing: Yes, fully developed and tested

D.2 Have NQF-endorsed measures been reviewed to identify if there are similar or related measures?
   Yes

(for NQF staff use) Have all conditions for consideration been met?
   Staff Notes to Steward (if submission returned):

Staff Notes to Reviewers (issues or questions regarding any criteria):

Staff Reviewer Name(s):

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1. IMPORTANCE TO MEASURE AND REPORT

Extent to which the specific measure focus is important to making significant gains in health care quality (safety, timeliness, effectiveness, efficiency, equity, patient-centeredness) and improving health outcomes for a specific high impact aspect of healthcare where there is variation in or overall poor performance. Measures must be judged to be important to measure and report in order to be evaluated against the remaining criteria.

1a. High Impact

(for NQF staff use) Specific NPP goal:

1a.1 Demonstrated High Impact Aspect of Healthcare: Frequently performed procedure, High resource use, Severity of illness, Patient/societal consequences of poor quality

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 adult population, outcome studies have shown an association between dose of hemodialysis and clinical outcomes [3,4]. No equivalent large scale clinical trials have been conducted in the pediatric population but smaller scale observational studies support the association between delivered dialysis dose and patient outcomes [5] including the potential for improved growth with intensive hemodialysis regimens [6]. In considering target spKt/V, the pediatric population should receive at least an spKt/V of 1.2, which is the minimum requirement for the adult population in order to allow for the increased nutritional needs of
children. Analysis of CPM data further support this cut-off since 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 [5]. A higher target KT/V may be necessary in the pediatric population given the increased dietary needs to ensure growth, but there is insufficient evidence to support increasing target KT/V based on hospitalization rates and mortality. Furthermore, a proportion of pediatric patients receive a dialysis dose below the target adult spKT/V suggesting that even with this target, there is room for improvement in quality of care.

This proposed measure differs from the corresponding adult adequacy measure in that the measure applies to patients receiving four dialysis treatments a week. Analysis of 2007 claims data (N=312 patients with first Medicare dialysis claim on or before January 1, 2007) suggest that in 5.6% of patient-weeks, dialysis sessions occurred four times per week. Given that this is not an insignificant proportion, these patients are included in this measure. Furthermore, there were three or four dialysis sessions in approximately 88% of patient-weeks. Based on these results it is evident that by restricting the denominator to hemodialysis patients receiving dialysis three or four times weekly, the measure will be applicable to most pediatric hemodialysis patients.

1a.4 Citations for Evidence of High Impact:

1b. Opportunity for Improvement

1b.1 Benefits (improvements in quality) envisioned by use of this measure: In considering target spKT/V, the pediatric population should receive at least an spKT/V of 1.2, which is the minimum requirement for the adult population in order to allow for the increased nutritional needs of children. Analysis of CPM data further support this cut-off since 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.

1b.2 Summary of data demonstrating performance gap (variation or overall poor performance) across providers:
Currently there is variation in the frequency of measurement of hemodialysis adequacy among the pediatric population. CPM data suggest 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. As stated in the 2006 Pediatric HD Adequacy Kidney Disease Outcomes Quality Initiative (KDOQI) guidelines rationale, monthly evaluation of HD adequacy is critical among the pediatric population, who are frequently growing and requiring changes in dose. Furthermore, analysis of facilities in the 2008 CPM project with more than one pediatric patient indicated that the percent of patients with Kt/V of 1.2 was 90% or higher in only 68% of facilities.

1b.3 Citations for data on performance gap:
Internal analysis of CPM data.

1b.4 Summary of Data on disparities by population group:
Observational pediatric data exist showing that older, larger, and African-American children are less likely to receive an spKT/V greater than 1.2 consistently [1]. Additionally, 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 (β=0.13, p<0.05) and among Nonblack patients compared to Black patients (β=0.22, p<0.001) [2].
1b.5 Citations for data on Disparities:

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): In the adult population, outcome studies have shown an association between dose of hemodialysis and clinical outcomes [1,2]. There is no indication that the pediatric population should receive an spKt/V dose lower than the adult population. This cut-off is also supported by an analysis of CPM data in which Gorman G, et al [3] found that adolescents with spKt/V below 1.2 had a significantly increased risk of hospitalization as compared to those with spKt/V of 1.2-1.4.

Large scale clinical trials have not been conducted in the pediatric hemodialysis population, however, smaller scale observational studies support the association between delivered hemodialysis dose and patient outcomes including the potential for improved growth with intensive hemodialysis regimens [3, 4].

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):

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 Clinical TEP considered higher target levels for the pediatric population since pediatric patients require increased nutritional needs to allow for growth. However, there is currently insufficient evidence to support increasing target Kt/V based on hospitalization rates and mortality, although there is evidence that increasing target Kt/V may improve growth in pediatric dialysis patients [1].


1c.9 Quote the Specific guideline recommendation (including guideline number and/or page number):
8.3.1 Children should receive at least the delivered dialysis dose as recommended for the adult population. (A)

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

Rating: C=Completely; P=Partially; M=Minimally; N=Not at all; NA=Not applicable
1c.12 Rating of strength of recommendation (also provide narrative description of the rating and by whom):
KDOQI CPG 8.3.1 rating strength grade is 'A'. The recommendation for Grade A guidelines states 'It is strongly recommended that clinicians routinely follow the guideline for eligible patients. There is strong evidence that the practice improves health outcomes.'

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

1c.14 Rationale for using this guideline over others:
Limited hemodialysis clinical practice guidelines exist for the pediatric population. In addition to the KDOQI clinical practice guidelines developed by the National Kidney Foundation, the 2005 CARI guidelines (Caring for Australians with Renal Impairment) also present guidelines for pediatric hemodialysis adequacy. The CARI guidelines present similar recommendations as the KDOQI, stating that delivered dialysis for children should at least equal doses recommended for adult patients.

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

Steering Committee: Was the threshold criterion, Importance to Measure and Report, met?
Rationale:
1

2. SCIENTIFIC ACCEPTABILITY OF MEASURE PROPERTIES

Extent to which the measure, as specified, produces consistent (reliable) and credible (valid) results about the quality of care when implemented. (evaluation criteria) Eval Rating

2a. MEASURE SPECIFICATIONS

S.1 Do you have a web page where current detailed measure specifications can be obtained?
S.2 If yes, provide web page URL:

2a. Precisely Specified

2a.1 Numerator Statement (Brief, text description of the numerator - what is being measured about the target population, e.g. target condition, event, or outcome): Number of patients in the denominator whose delivered dose of hemodialysis (calculated from the last measurements of the month using the UKM or Daugirdas II formula) was a spKt/V>=1.2.

2a.2 Numerator Time Window (The time period in which cases are eligible for inclusion in the numerator): Number of patients in the denominator whose delivered dose of hemodialysis (calculated from the last measurements of the month using the UKM or Daugirdas II formula) was a spKt/V>=1.2.

2a.3 Numerator Details (All information required to collect/calculate the numerator, including all codes, logic, and definitions): The numerator will be determined by counting the patients in the denominator for whom "Kt/V Hemodialysis Method" is 'Daugirdas II' OR 'UKM' AND "Kt/V" is greater than or equal to 1.2.

2a.4 Denominator Statement (Brief, text description of the denominator - target population being measured): Number of pediatric (<18 years old) in-center HD patients who have been on hemodialysis for 90 days or more and dialyzing 3 or 4 times weekly.

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).

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. C - The USPSTF recommends against routinely providing the service. There may be considerations that support providing the service in an individual patient. D - 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.
2a.5 Target population gender: Female, Male
2a.6 Target population age range: Pediatric patients less than 18 years old.

2a.7 Denominator Time Window (The time period in which cases are eligible for inclusion in the denominator):
The entire calendar month.

2a.8 Denominator Details (All information required to collect/calculate the denominator - the target population being measured - including all codes, logic, and definitions):
The 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 who have been on dialysis for 90 days or longer and “Sessions per Week” is equal to 3 or 4. 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 hemodialysis, patients on hemodialysis<90 days, patients receiving dialysis <3x/week or greater than 4x/week, patients not in the facility for the entire calendar month.

2a.10 Denominator Exclusion Details (All information required to collect exclusions to the denominator, including all codes, logic, and definitions):
Exclusions to this measure include patients receiving dialysis 5 times or more per week, as in those with diseases such as oxalosis in whom frequent dialysis may result in minimal changes in urea clearance with the resulting low spKt/V for a single session. Patients receiving dialysis two times a week were also excluded as these patients likely have residual renal function, which is a component of clearance not currently captured.

2a.11 Stratification Details/Variables (All information required to stratify the measure including the stratification variables, all codes, logic, and definitions):
Stratification of target values by age was considered, with higher targets for younger patients, however there are insufficient data to support any stratified target measures at this time.

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 who have been on dialysis for 90 days or longer and “Sessions per Week” is equal to 3 or 4. 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.

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.
The numerator will be determined by counting the patients in the denominator for whom "Kt/V Hemodialysis Method" is 'Daugirdas II' OR 'UKM' AND "Kt/V" is greater than or equal to 1.2.

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
http://www.projectcrownweb.org/crown/index.php

2a.29-31 Data dictionary/code table web page URL or attachment: URL

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

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) ranged from 0.94 to 0.96. The average level of concurrence (LOC) for missing vs. non-missing was 92%, and for non-missing data only was 100%. Generally, acceptable agreement rates are 0.80 or higher and concurrence targets are 90% or higher.

2c. Validity testing

2c.1 Data/sample (description of data/sample and size): This measure was established on the basis of face validity. Evidence suggests the importance of achieving hemodialysis adequacy target levels based on...
Improvement in clinical outcomes based on spKt/V of 1.2. All clinical TEP members agreed that this measure will improve quality of care for pediatric in-center hemodialysis patients.

2c. Analytic Method (type of validity & rationale, method for testing):
Face validity is the only validity assessed, therefore testing is not applicable.

2c.3 Testing Results (statistical results, assessment of adequacy in the context of norms for the test conducted):
Face validity is the only validity assessed as there is no gold standard for defining hemodialysis adequacy. However, this measure is considered as valid based on the association between achievement of spKt/V target levels and improvement in clinical outcomes as presented above.

### 2d. Exclusions Justified

#### 2d.1 Summary of Evidence supporting exclusion(s):
Exclusions are not supported by evidence. However, they are limited to those with a compelling clinical rationale and are precisely defined.

#### 2d.2 Citations for Evidence:
N/A

#### 2d.3 Data/sample (description of data/sample and size):
N/A

#### 2d.4 Analytic Method (type analysis & rationale):
N/A

#### 2d.5 Testing Results (e.g., frequency, variability, sensitivity analyses):
N/A

### 2e. Risk Adjustment for Outcomes/ Resource Use Measures

#### 2e.1 Data/sample (description of data/sample and size):
No risk adjustments are necessary for this measure.

#### 2e.2 Analytic Method (type of risk adjustment, analysis & rationale):
N/A

#### 2e.3 Testing Results (risk model performance metrics):
N/A

#### 2e.4 If outcome or resource use measure is not risk adjusted, provide rationale:
N/A

### 2f. Identification of Meaningful Differences in Performance

#### 2f.1 Data/sample from Testing or Current Use (description of data/sample and size):
Data from the ESRD Clinical Performance Measures Project were used to perform analyses on determining differences in performance in the hemodialysis facilities. Data were reported on 693 hemodialysis patients from total of 252 facilities treating pediatric hemodialysis patients, only 93 had more than one pediatric patient.

#### 2f.2 Methods to identify statistically significant and practically/meaningfully differences in performance (type of analysis & rationale):
Facility level percentages and percentiles were assessed, which is similar to what is reported in the ESRD CPM Annual Report.

#### 2f.3 Provide Measure Scores from Testing or Current Use (description of scores, e.g., distribution by quartile, mean, median, SD, etc.; identification of statistically significant and meaningfully differences in performance):
Of the 93 facilities treating more than one pediatric hemodialysis patient, only 68% reported Kt/V of 1.2 or higher in 90% of patients. Additional analyses of these 93 facilities indicated the facility-level percent of
pediatric HD patients with Kt/V=1.2 ranged from 0 to 100%, and the 25th, 50th, and 75th percentiles were 83%, 100%, and 100%, respectively.

2g. Comparability of Multiple Data Sources/Methods

2g.1 Data/sample (description of data/sample and size): CROWNWeb. Phase 1 and 2 CROWNWeb Beta Testing Data: Data are based on the 18 facilities participating in Phase 1 and the 180 facilities participating in Phase 2 plus about 3000 additional batch-submission facilities in CROWNWeb. These data include about 60% of dialysis facilities and 75% of dialysis patients and are heavily weighted towards large dialysis organization facilities.

2g.2 Analytic Method (type of analysis & rationale): Multiple data sources are not allowed for this measure, and therefore testing is not needed.

2g.3 Testing Results (e.g., correlation statistics, comparison of rankings): N/A

2h. Disparities in Care

2h.1 If measure is stratified, provide stratified results (scores by stratified categories/cohorts): N/A

2h.2 If disparities have been reported/identified, but measure is not specified to detect disparities, provide follow-up plans:

Stratification by race may be considered since a published study based on CPM data suggests that African-American children may be less likely to receive an spKt/V greater than 1.2 consistently. Stratification by gender may also be considered based on results from an analysis of NAPRTCS (North American Pediatric Renal Transplant Cooperative Study) data, which showed female pediatric patients received significantly higher Kt/V doses than males.

3a. Meaningful, Understandable, and Useful Information

3a.1 Current Use: Not in use but testing completed

3a.2 Use in a public reporting initiative (disclosure of performance results to the public at large) (If used in a public reporting initiative, provide name of initiative(s), locations, Web page URL(s). If not publicly reported, state the plans to achieve public reporting within 3 years):
The ESRD Clinical Performance Measures Project (URL) presents data on the pediatric ESRD population.

3a.3 If used in other programs/initiatives (If used in quality improvement or other programs/initiatives, name of initiative(s), locations, Web page URL(s). If not used for QI, state the plans to achieve use for QI within 3 years):
Testing of Interpretability  (Testing that demonstrates the results are understood by the potential users for public reporting and quality improvement)

3a.4 Data/sample (description of data/sample and size): This has not been performed.

3a.5 Methods (e.g., focus group, survey, QI project): N/A

3a.6 Results (qualitative and/or quantitative results and conclusions): N/A

3b/3c. Relation to other NQF-endorsed measures

3b.1 NQF # and Title of similar or related measures:
NQF # 0249 ESRD- HD Adequacy CPM III: Minimum Delivered Hemodialysis Dose for ESRD hemodialysis patients undergoing dialytic treatment for a period of 6 months or greater
NQF # 250 ESRD- HD Adequacy CPM III: Minimum Delivered Hemodialysis Dose for ESRD hemodialysis patients undergoing dialytic treatment for a period of 90 days or greater.

(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 partially harmonized with the adult measure. The adult measure only includes patients receiving thrice weekly dialysis and also requires patients to have a residual renal function (if measured in the last three months) less than 2 ml/min/1.73m². For pediatric patients, the TEP agreed it is important to include pediatric patients receiving dialysis 4 times per week based since a proportion of pediatric patients receive this frequency of hemodialysis. In an analysis of 2007 claims data, 5.6% of patient-weeks had dialysis sessions four times per week. With regards to the incorporation of residual renal function in the calculation of adequacy, this was not added to the pediatric measure for several reasons: 1) Published studies evaluating dialysis adequacy in the pediatric population do not include residual renal function, 2) RRF changes continuously with age in the pediatric population and 3) RRF is difficult to measure among pediatric patients.

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.

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.

TAP/Workgroup: What are the strengths and weaknesses in relation to the subcriteria for Usability?

Steering Committee: Overall, to what extent was the criterion, Usability, met?
Rationale:

4. FEASIBILITY

Extent to which the required data are readily available, retrievable without undue burden, and can be implemented for performance measurement. (evaluation criteria)

Rating: C=Completely; P=Partially; M=Minimally; N=Not at all; NA=Not applicable
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).

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.

4c. Exclusions

4c.1 Do the specified exclusions require additional data sources beyond what is required for the numerator and denominator specifications?
No

4c.2 If yes, provide justification.

4d. Susceptibility to Inaccuracies, Errors, or Unintended Consequences

4d.1 Identify susceptibility to inaccuracies, errors, or unintended consequences of the measure and describe how these potential problems could be audited. If audited, provide results.
Data elements for this measure are already being collected and are unlikely to be susceptible to inaccuracies, errors or unintended consequences.

4e. Data Collection Strategy/Implementation

4e.1 Describe what you have learned/modified as a result of testing and/or operational use of the measure regarding data collection, availability of data/missing data, timing/frequency of data collection, patient confidentiality, time/cost of data collection, other feasibility/implementation issues:
Because data elements required for this measure are already being collected as part of the ESRD CPM, facilities are familiar with data required for this measure. This reduces the likelihood of errors in the data collection process.

4e.2 Costs to implement the measure (costs of data collection, fees associated with proprietary measures):
The estimated data collection burden and associated cost estimate is presented in Tables 1-3 in the Federal Register. Vol. 73, No. 73 page 20469.
URL: http://www.cms.gov/CFCsAndCoPs/downloads/ESRDfinalrule0415.pdf

4e.3 Evidence for costs:
See above reference to Federal Register.

4e.4 Business case documentation: 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.


TAP/Workgroup: What are the strengths and weaknesses in relation to the subcriteria for Feasibility?
Steering Committee: Overall, to what extent was the criterion, Feasibility, met?
Rationale:

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RECOMMENDATION
(for NQF staff use) Check if measure is untested and only eligible for time-limited endorsement.

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Steering Committee: Do you recommend for endorsement?
Comments:

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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? Every three years
Ad.9 When is the next scheduled review/update for this measure? 2013
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<th>Ad.10</th>
<th>Copyright statement/disclaimers:</th>
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<td>Ad.11 -13</td>
<td>Additional Information web page URL or attachment:</td>
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<td>Date of Submission (MM/DD/YY):</td>
<td>09/28/2010</td>
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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:
  - Intermediate outcome - evidence that the measured intermediate outcome (e.g., blood pressure, Hba1c) leads to improved health/avoidance of harm or cost/benefit.
  - 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).
  - 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.
  - 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.
  - Access - evidence that an association exists between access to a health service and the outcomes of, or experience with, care.
  - 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.

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).

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;

OR

rationale/data support no risk adjustment.

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.

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