

**End Stage Renal Disease (ESRD)
Quality Measure Development and Maintenance
Pediatric Peritoneal Dialysis Adequacy Clinical Technical Expert Panel Draft Summary Report
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Technical Expert Panel Summary

The Centers for Medicare & Medicaid Services (CMS) has contracted with Arbor Research Collaborative for Health (Arbor Research) and the University of Michigan Kidney Epidemiology and Cost Center (UM-KECC) to develop End-Stage Renal Disease (ESRD) Quality Measures (QMs) for the following four measure areas:

- Mineral and Bone Disorder
- Hemodialysis Adequacy
- Preventive Care (Pneumococcal, Hepatitis B, and Influenza Vaccinations)
- Dialysis Adequacy for Pediatric Patients (Peritoneal Dialysis Adequacy [PD])

The purpose of the project is to develop measurements that can be used to provide quality care to Medicare beneficiaries.

Technical Expert Panel Objectives

The objectives of these ESRD C-TEPs were described in the charter that was approved by the C-TEPs. The C-TEPs were charged with providing expertise and input to Arbor Research on the development and implementation of measures that will be used to assess and improve the quality of care for Americans with ESRD. The C-TEPs were to provide guidance and assist in the development and specification of new quality measures in specific clinical areas. In addition, the C-TEP members were to consider potential measures using the framework of CMS and the National Quality Forum (NQF). The four evaluation criteria are: [*importance*](#), [*scientific acceptability*](#), [*feasibility*](#), and [*usability*](#).

Technical Expert Panel Meeting

The Preventive Care, Mineral and Bone Disorder, and Hemodialysis Adequacy TEP met in Baltimore, MD on April 16-17, 2013. The Pediatric Peritoneal Dialysis Adequacy TEP met via conference call on April 11 and April 17, 2013.

The TEPs were comprised of individuals with the following areas of expertise and perspectives:

- Topic Knowledge: ESRD
- Performance Measurement
- Quality Improvement
- Consumer Perspective
- Purchaser Perspective
- Health Care Disparities

The following individuals participated in this TEP:

Name	Title	Organization	Measure Area	Conflict of Interest Disclosure
Deepa Chand, MD MHSA	Medical Director, Kidney Dialysis	Akron Children's Hospital Medical Center	Pediatric Peritoneal Dialysis Adequacy	Research support from Gambro, Vifo
Annabelle Chua, MD	Assistant Professor, Pediatrics	Baylor College of Medicine/Texas Children's Hospital	Pediatric Peritoneal Dialysis Adequacy	Industry sponsored studies by Amgen, Abbvie
Barbara Fivush, MD MHSA	Chief of Pediatric Nephrology	Johns Hopkins Children's Center	Pediatric Peritoneal Dialysis Adequacy	None
Joseph Flynn, MD MS	Professor of Pediatrics	University of Washington School of Medicine	Pediatric Peritoneal Dialysis Adequacy	None
Bradley Warady, MD	Chief, Pediatric Nephrology; Director, Dialysis and Transplantation; Professor of Pediatrics	University of Missouri, Kansas City School of Medicine	Pediatric Peritoneal Dialysis Adequacy	Consultant for Baxter Healthcare

1. Introduction

This report summarizes the discussions and recommendations of the Pediatric Peritoneal Dialysis Adequacy Technical Expert Panel (TEP) meetings convened by conference call on April 11, 2013, and April 17, 2013. The consideration of potential measures of pediatric peritoneal dialysis adequacy were informed by a review of relevant clinical guidelines and literature as part of an environmental scan conducted by Arbor Research and UM-KECC. Potential measures were evaluated using the criteria for clinical performance measures adopted by the National Quality Forum (NQF) and CMS. These criteria include each measure's importance, scientific acceptability, feasibility, and usability.

2. Specific Considerations for the Pediatric ESRD Population

In considering potential measures, the TEP recognized that large scale clinical trials evaluating target peritoneal dialysis (PD) adequacy for the pediatric population do not exist. Due to the low prevalence of stage 5 CKD among pediatric patients, high renal transplantation rate, and difficulty of determining measurable study end points, longitudinal studies on pediatric hemodialysis (HD) adequacy have not been performed and clinical evidence regarding PD adequacy are primarily based on observational studies. Furthermore, existing clinical practice guidelines for the management of pediatric ESRD patients are opinion- rather than evidence-based.

Similar to the prior approach to developing HD adequacy measures for the pediatric population, the pediatric PD adequacy measures were also framed in the context of the unique aspects of the management of pediatric ESRD patients. First, among children, outcome measures such as mortality and hospitalizations occur infrequently and other outcomes such as linear growth, school performance and attendance, and cognitive development should be considered. Second, pediatric patients have a wide variation in physiology by age and the clinical approach may differ particularly in younger pediatric patients. Finally, the majority of pediatric ESRD patients receive care in primarily adult hemodialysis units, and even within pediatric units wherein greater than 50% of patients are of pediatric age, the number of pediatric patients within each unit is small. Indeed, analysis of claims data suggests that the majority of non-pediatric units dialyze one or two patients under the age of 18 years, so that the impact of each patient on a facility-level measure needs to be taken into consideration. Despite this, the TEP discussed that in these primarily adult units, even greater attention should be provided to the one or two pediatric patients who are treated.

Prior to discussing specific pediatric PD adequacy measures, the TEP members agreed that since clinical performance measures for pediatric patients currently do not exist, measures should be developed even if they are based on preliminary or limited available data. Furthermore, these pediatric PD adequacy targets should be no lower than existing adult PD adequacy targets since generally, pediatric patients' greater metabolic demands require higher adequacy targets in terms of small solute clearance.

Currently there are no NQF endorsed measures for pediatric patients (age<18 years old) on peritoneal dialysis (PD).

3. Overview of Measure Areas to be Discussed

The Pediatric PD Adequacy TEP was asked to consider the following topic areas: method of measurement for PD adequacy in the pediatric population, frequency of measurement of PD adequacy in the pediatric population, and target Kt/V in pediatric patients on PD. Additionally, the TEP felt it was important to discuss the assessment of peritoneal membrane function as this may impact on achievement of adequacy targets in peritoneal dialysis. Finally the TEP also raised the importance of fluid weight management as an important component of peritoneal dialysis adequacy.

4. Clinical Guideline Review and Literature Review

Prior to discussing potential measures, Arbor Research and UM-KECC presented the TEP with a description of existing clinical guidelines and literature for peritoneal dialysis adequacy in the pediatric population. An overview of the pediatric PD adequacy guidelines is shown below.

Guideline Source	Adequacy Target
KDOQI (2006)	Peritoneal and kidney clearance should be a Kt/V urea of at least 1.8/week
Canadian Association (2006)	Awaiting KDOQI guidelines (mentioned a weekly Kt/V (dialysis and residual renal function) of 2.1
European Pediatric PDWG (2005)	Kt/V>2
British Association (2008)	Combined urinary and peritoneal Kt/V urea of 1.7/week or creatinine clearance of 50L/week/1.73m ²
Guideline Source	Frequency of Calculation
KDOQI	Within the first month after initiation then at least once every 6 months;
Canadian Association	Minimum of 2x over first 6 months, then 3 monthly thereafter or if there is a change in prescription or recent peritonitis
European Pediatric PDWG	Not specified
British Association	Both peritoneal and RRF should be measured at least 6 monthly
Guideline Source	Measurement of Volume of distribution
KDOQI	Anthropometric prediction equations based on height and weight. Use of Gehan and George equations? Sex-specific normograms
Canadian	Not specified

Association	
European Pediatric PDWG	Not specified
British Association	Not specified
Guideline Source	Measurement of Residual Renal Function
KDOQI	For those with RRF- 24 hour urine collection for volume and solute clearance determination every 3 months (RRF defined as those with urine Kt/V urea of ≥ 0.1 /week). Averaged urea and Ccr from a timed urine collection is the most accurate means but urine Kt/V urea alone is recommended because of simplicity of calculation
Canadian Association	Average of weekly clearances of creatinine and urea derived from a 24 hour urine collection with measurements of creatinine and urea in blood and urine
European Pediatric PDWG	Not specified
British Association	No specific recommendation

The TEP reviewed clinical practice guidelines summarized above for pediatric PD patients, including the KDOQI 2006 update, the British Association for Paediatric Nephrology (2008), Canadian Association of Pediatric Nephrologists (2005), and European Pediatric Peritoneal Working Group (2005). The TEP chair, who was also the chairman for the KDOQI pediatric PD guidelines development group, stated that the KDOQI guideline for the specific target of weekly Kt/V of at least 1.8/week (NKF 2006) was based on clinical opinion due to the lack of available pediatric data. Additionally, it was noted that the Canadian guidelines refer to the KDOQI 2006 guideline suggestions.

The TEP briefly discussed some findings from the literature. One study showed a weekly Kt/V target of 1.8 was associated with better albumin levels in adult PD patients. Another study showed a survival advantage among adult PD patients with a weekly Kt/V of at least 1.8, whereas the ADEMEX study (Paniagua 2002) did not show a clinical benefit with weekly Kt/V of at least 1.7 in adult CAPD patients (Lo 2005). Also, small studies on pediatric PD patients have suggested a relationship between outcomes including growth and solute clearance (Warady 2001, Holtta 2000).

5. Proposed PD Adequacy Measures for Pediatric Patients

Measure 1:

The percent of pediatric peritoneal dialysis patient-months with Kt/V greater than or equal to 1.8 (dialytic + residual) during the six month reporting period.

Denominator: All pediatric (< 18 years old) peritoneal dialysis patients who have been on PD for at least 90 days.

Numerator: Patients are included in the numerator if delivered PD was a weekly Kt/V urea (dialytic + residual) of at least 1.8 during the six month reporting period.

Measure details:

- If RRF is to be incorporated in the Kt/V calculation, this will be calculated using the mean of urea and creatinine clearances derived from 24 hour urine collection
- Total body water (V) should be estimated by one of the following pediatric specific V approximation methods:
 - Prediction equation based upon heavy water dilution
 - Males: $TBW = 0.10 (ht \times wt)^{0.68} - 0.37 (wt)$
 - Females: $TBW = 0.14 (ht \times wt)^{0.64} - 0.35 (wt)$
 - Simplified V estimating equations:
 - Males: $TBW = 20.88 \times BSA - 4.29$
 - Females: $TBW = 16.92 \times BSA - 1.81$
 - Sex specific normograms from the KDOQI PD guidelines for the pediatric population update from 2006

Exclusions: Hemodialysis patients, adult patients (age 18 years or older), pediatric peritoneal dialysis patients on dialysis < 90 days.

Additional comments: There is evidence that dialysis prescriptions should be individualized, and this should be guided by a Peritoneal Equilibration Test (PET) no sooner than four weeks after initiating dialysis. A PET should also be performed if ultrafiltration or adequacy targets are not met.

Measure 2:

The percent of pediatric peritoneal dialysis patients with documented adequacy (dialytic+residual) measurements during the six month reporting period.

Denominator: All pediatric (< 18 years old) peritoneal dialysis patients who have been on PD for at least 90 days.

Numerator: Patients are included in the numerator if a weekly Kt/V urea (dialytic + residual) measurement was documented during the six-month reporting period.

Exclusions: Hemodialysis patients, adult patients (age 18 years or older), pediatric peritoneal dialysis patients on dialysis < 90 days.

6. Summary of TEP discussions for the proposed measures

The TEP discussed the existing adult NQF endorsed measure (NQF #318). The TEP acknowledged that the pediatric proposed measures are not harmonized with NQF measure #318. The pediatric measures propose a Kt/V target of 1.8/week and the performance of a Kt/V measure measured at least once every 6 months, compared to a target of 1.7/week measured at least once every 4 months for the adult measure. Justifications for these differences are summarized below:

6.1 Justification for Measure 1: Kt/V target of 1.8/week

- Recognizing that limited evidence in the pediatric population exists, clinical practice guidelines and clinical opinion support the recommendation that target clearance in pediatric patients should meet or exceed adult standards.
- Kt/V of 1.8/week or greater in adult PD patients was associated with better serum albumin levels (a predictor of survival) (Paniagua 2002).
- ADEMEX did not show clinical benefit with Kt/V > 1.7/week in adult CAPD patients (JASN 2002).
- In a study of adult CAPD patients, Kt/V > 1.8/week may be optimal based on survival analysis (Lo, KI 2005).
- In small studies, pediatric data suggest a positive relationship between clinical outcomes, including growth and total solute clearance (Warady 2001, Holtta 2000).
- Kt/V of 1.8 is the generally accepted target in the community and there may be a potential for confusion if the measure target is not the target recommended by clinical practice guidelines.
- There is also the consideration that smaller patients may have higher Kt/V because the V of these patients will be smaller and the resulting mathematical calculation of Kt/V may be higher. This may support a higher target of 1.8/week as compared to 1.7/week.

The TEP also reviewed analyses presented by Arbor Research/UM-KECC of the achievement of several alternative pediatric PD adequacy measures. These analyses considered targets of Kt/V ≥ 1.7 and Kt/V ≥ 1.8, four and six month reporting periods, and measures that included and excluded missing data for Kt/V. Analyses were performed at both the patient and facility levels. These analyses used both CROWNWeb data and Medicare claims data for pediatric PD patients. Patient level analyses showed that among the 227 Medicare pediatric PD patients with Kt/V reported in the claims, 83% (189) of patients met the Kt/V target of 1.7 and 78% (N=178) of patients had a Kt/V of at least 1.8 (Table 1). In CROWNWeb, there were a total of 427 pediatric PD patients during the 4 month time period from May 2012 through August 2012. A total of 37% (N=158) and 35% (N=149) met the Kt/V targets of 1.7 and 1.8, respectively. However, approximately 55% (N=233) of these patients did not have a Kt/V value reported during the 4 month time period. Among 194 patients with a Kt/V value reported in CROWNWeb, 81% and 77% of patients had a Kt/V of at least 1.7 and 1.8, respectively (Table 2). The CROWNWeb data limitations of non-finalized data (data collection is not closed and there is large proportion of missing data) were noted during the presentation.

Table 1. Pediatric PD Adequacy Measure using Medicare claims data from May 2012-August 2012

PD patients who meet denominator criteria:	Frequency	Percent of patients among those with Kt/V value reported (N=194)	Percent of all PD pediatric patients (n=427)
with a Kt/V value during the four month period greater than or equal to 1.7	158	81.4%	37.0%*
with a Kt/V value during the four month period greater than or equal to 1.8	149	76.8%	34.9%

Table 2. Pediatric PD Adequacy Measure using CROWNWeb data from May 2012-August 2012

PD patients who meet denominator criteria:	Frequency	Percent of patients among those with Kt/V value reported (N=227)	Percent of all PD pediatric patients (N=312)
with a Kt/V value during the four month period greater than or equal to 1.7	189	83.2%	60.6%
with a Kt/V value during the four month period greater than or equal to 1.8	178	78.4%	57.1%

Facility-level analyses were presented by number of pediatric PD patients using all available claims data from July 2010 through December 2012. Results indicated that the facilities with fewer pediatric PD patients had higher levels of performance. The median percentage of pediatric PD patients with Kt/V of at least 1.8 measured at least once every 6 months was 92% for facilities with 1-4 pediatric PD patients, compared to 83% among facilities with 5-9 pediatric PD patients, and 71% with 20 or more.

These analyses were also displayed by facility size (number of pediatric PD patients), ownership type (chain or independent), and facility type (hospital-based, freestanding, or hospital satellite) categories. Results showed a higher percent of pediatric PD patients achieved a weekly Kt/V target of 1.8 in facilities with fewer than 15 pediatric PD patients (vs. 15 or more patients), free-standing

facilities (vs. hospital-based and hospital-satellite facilities), and chain facilities (vs. independently owned).

CROWNWeb analyses of residual renal function assessed in Kt/V overall and categorized by age and analyses on missing PD Kt/V were presented. Results showed that RRF is not assessed in pediatric PD Kt/V values for 25.4% and data are missing for 54.6% of pediatric PD patients. RRF is not assessed in Kt/V more often for older pediatric patients ages 13-17, compared to younger patients. Older pediatric patients, ages 13-17, had a lower percent achieving the targets compared to younger patients if missing Kt/V values are excluded. A higher percentage of pediatric PD patients were missing Kt/V values in facilities with 15 or more pediatric PD patients (vs. facilities with less than 15 patients).

6.2 Justification for Measure 2: Six month reporting period

- The corresponding adult PD measure requires assessment of Kt/V at four month intervals; however, the rationale for this interval in the adult population is unclear.
- For pediatric patients, the interval of measurement should take into consideration the practicality of performing adequacy measurements where collection of PD effluent fluid and residual urine may be more challenging.
- This measure assumes that standard practice of monthly clinical assessment of pediatric PD patients is conducted. This assumption will be documented in the measure submission forms.
- Clinical practice guidelines indicate measurement of Kt/V at least once every six months in this population, and preliminary analyses suggest that this is currently practiced by the community. Deviating from this practice may be confusing to the nephrology community.
- Finally, there is no clear evidence that supports the need to increase the frequency of measurement to four month intervals.
- The TEP also noted that although Kt/V should be measured a minimum of every 6 months, this may be more frequent depending on the occurrence of events that may reduce solute clearance such as peritonitis.

The TEP reviewed analyses of the frequency of Kt/V measurement using both Medicare claims and CROWNWeb data. Among pediatric PD patients with Medicare claims data during May 2012 to October 2012, a total of 253 (75%) of the 337 patients had at least one non-missing Kt/V value. A total of 52 (15%) of patients had a Kt/V reported in every month. In CROWNWeb from May 2012 to October 2012, a total of 184 (49%) pediatric PD patients had at least one Kt/V value reported, and 6% (N=23) had a Kt/V value reported in every month. These analyses suggest that a performance gap for measurement of Kt/V exists in the pediatric PD population and a process measure for frequency of Kt/V measurement may improve the practice of measuring dialysis adequacy.

The TEP also considered harmonization of both measures with the corresponding adult measure. However, for the reasons summarized above, the TEP believed that the needs of the pediatric population and the evidence as summarized outweigh the importance of harmonization with the adult measure. There was also a discussion regarding the exclusion criteria for these measures, particularly for the Kt/V target measure. A TEP member stated that achieving a Kt/V target of at least 1.8/week may be more challenging among patients with genetic conditions that may reduce the volume of PD fluid

during each exchange. The TEP concluded that this population should not be excluded since these conditions are exceedingly rare and therefore do not justify exclusion. Furthermore, this approach is similar to the 2010 pediatric anemia TEP discussion where pediatric dialysis patients with sickle cell anemia were not excluded from the anemia management measures.

The work group discussed the difficulty in collecting urine to determine RRF in patients less than 2 years of age. In situations where urine cannot be collected, the TEP agreed that Kt/V measurement should be based only on PD solute clearance and the target should remain at 1.8.

6.3 Justification for Method of measurement of total body water (V) and residual renal function (RRF)

The TEP felt it would be important to make a recommendation on the methodology for measurement of V. There is evidence in the literature that the method of measurement of V among pediatric patients is different from adults and, therefore, the pediatric measurement methods need to become the standard practice in the pediatric nephrology community. For the adult measure, residual renal function was included in the calculation of Kt/V only if the urine output exceeded 100ml/d. This definition of presence of residual renal function based on urine output is not valid in the pediatric population. For this reason, the pediatric measure assumes that RRF is always considered in the assessment of Kt/V. Should there be no RRF or in situations where RRF cannot be measured (as may occur in pediatric patients <2 years of age where collection of urine is not feasible), the Kt/V measurement will be based solely on dialysate clearance as described above. If RRF is to be included in the calculation, the TEP agreed that the method used to calculate RRF should be the mean of urea and creatinine clearance, which is consistent with the adult methodology.

Adult methods for calculating V are not valid for the pediatric population. The TEP reviewed 3 potential measures for approximation of V in the pediatric population which includes 1) heavy water dilution (gold standard), 2) gender-specific prediction equations that were compared against heavy water dilution (Morgenstern 2006) and 3) use of normograms that were based on estimating equations for the pediatric PD population. The TEP agreed that methods 2 or 3 are the most appropriate in the pediatric PD population. The KDOQI guidelines also support the use of these methodologies. Therefore, all three methods for calculating V are included in the numerator measure details.

6.4 Other Considerations for Pediatric PD Adequacy Measure Development

There were two other areas related to PD adequacy that were discussed in addition to the Kt/V target: (1) performance of a Peritoneal Equilibration Test (PET) and (2) ultrafiltration as a measure of adequacy.

Performance of a Peritoneal Equilibration Test (PET)

The TEP discussed the possibility of a process measure on the performance of a PET test. The TEP discussed that although the performance of a PET test is not routine, clinical guidelines support the assessment of peritoneal membrane characteristics when PD prescription is developed. Furthermore, clinical situations may indicate the performance of a PET such as in the presence of inadequate ultrafiltration. However, review of the literature and clinical guidelines do not specify the routine performance of a PET test.

The TEP reviewed analyses performed on the data collected in the 2006 Clinical Performance Measures (CPM) project, which showed that PET results were reported for only 11% of pediatric patients in the study. Based on these findings and the lack of any data elements in CROWNWeb, the TEP decided that a guideline added to the proposed target measure would be the best place to educate the community on performing PET in pediatric PD patients. The TEP members agreed that PET should be a topic to revisit in future panels.

Ultrafiltration as a measure of adequacy

The TEP discussed the measure specifications of the NQF endorsed time-limited ultrafiltration measure (NQF # 1438) which includes pediatric patients and decided that this measure was appropriate for the pediatric PD population. The TEP members provided the following comments about the ultrafiltration topic area:

- Ultrafiltration is an important component of PD adequacy.
- Measurement of dry weight (time limited measure) is important but should be part of an overall assessment of every patient that would include: blood pressure, peritoneal dialysis drain volume on a monthly basis.
- Cardiovascular disease is the primary cause of mortality in patients with childhood-onset ESRD.
- Performance of the PET may assist in development of a PD prescription to optimize fluid management.

6.5 Feasibility

The TEP reviewed the data elements collected in CROWNWeb and determined that the proposed pediatric PD adequacy measures are feasible. Furthermore, facilities have been reporting weekly Kt/V for pediatric PD patients in Medicare claims since July 2010.

6.6 Usability

Dialysis adequacy calculated as Kt/V is currently used and reported in the adult HD and PD and pediatric HD adequacy populations.

7. Measure Area Gaps for the Pediatric ESRD Population

The TEP developed the following list of measure areas for discussion at future pediatric technical expert panels.

- Growth and nutrition
- Peritoneal equilibration test (PET)
- Transplant referral
- Quality of life
- Vascular access
- Education and rehabilitation
- Pediatric-specific vaccinations
- Peritonitis and hemodialysis-catheter infection

The TEP discussed investigating survival as an outcome for pediatric PD patients. One TEP member indicated that due to the small patient pool size and few deaths among pediatric PD patients, it would take several years to perform a clinical trial. The TEP agreed that extrapolation from the adult population is the best alternative at this time. Additionally, the TEP indicated that future studies in the pediatric PD population should consider other outcomes such as cardiovascular outcomes (i.e. left ventricular hypertrophy) or growth.

8. Conclusion

Our pediatric PD TEP discussed development of adequacy measures in the areas of a Kt/V target, measurement of residual renal function and total body water (V), performance of a peritoneal equilibration test (PET), and ultrafiltration. The TEP recommended two measures- 1) a Kt/V adequacy target measure and 2) a process measure for Kt/V measurement. Recommendations on measurement of RRF and V and performance of PET tests were also discussed. Much consideration was given to the deviation of the Kt/V measure specifications from the adult PD measure and justification lists were developed to support the decisions made. No measures or recommendations were made for ultrafiltration at this time. The TEP concluded that the current time-limited ultrafiltration measure is sufficient because it includes pediatric patients.

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