**National Quality Forum—Evidence (subcriterion 1a)**

**Measure Number** (*if previously endorsed*)**:** 1423

**Measure Title**: Minimum spKt/V for Pediatric Hemodialysis Patients

**IF the measure is a component in a composite performance measure, provide the title of the Composite Measure here:** Click here to enter composite measure #/ title

**Date of Submission**: 4/2/2019

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| **Instructions**  *Complete 1a.1 and 1a.2 for all measures. If instrument-based measure, complete 1a.3.*  *Complete* ***EITHER 1a.2, 1a.3 or 1a.4*** *as applicable for the type of measure and evidence.*  *For composite performance measures:*  *A separate evidence form is required for each component measure unless several components were studied together.*  *If a component measure is submitted as an individual performance measure, attach the evidence form to the individual measure submission.*   * All information needed to demonstrate meeting the evidence subcriterion (1a) must be in this form. An appendix of *supplemental* materials may be submitted, but there is no guarantee it will be reviewed. * If you are unable to check a box, please highlight or shade the box for your response. * Contact NQF staff regarding questions. Check for resources at [Submitting Standards webpage](http://www.qualityforum.org/Measuring_Performance/Submitting_Standards.aspx). |

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| **Note: The information provided in this form is intended to aid the Standing Committee and other stakeholders in understanding to what degree the evidence for this measure meets NQF’s evaluation criteria.**   1a. Evidence to Support the Measure Focus The measure focus is evidence-based, demonstrated as follows:   * Outcome: [**3**](#Note3) Empirical data demonstrate a relationship between the outcome and at least one healthcare structure, process, intervention, or service. If not available, wide variation in performance can be used as evidence, assuming the data are from a robust number of providers and results are not subject to systematic bias. * Intermediate clinical outcome: a systematic assessment and grading of the quantity, quality, and consistency of the body of evidence [**4**](#Note4)that the measured intermediate clinical outcome leads to a desired health outcome. * Process: [**5**](#Note5) a systematic assessment and grading of the quantity, quality, and consistency of the body of evidence [**4**](#Note4) that the measured process leads to a desired health outcome. * Structure: a systematic assessment and grading of the quantity, quality, and consistency of the body of evidence [**4**](#Note4) that the measured structure leads to a desired health outcome. * Efficiency: [**6**](#Note6) evidence not required for the resource use component. * For measures derived from patient reports, evidence should demonstrate that the target population values the measured outcome, process, or structure and finds it meaningful. * Process measures incorporating Appropriate Use Criteria: See NQF’s guidance for evidence for measures, in general; guidance for measures specifically based on clinical practice guidelines apply as well.   **Notes**  **3.** Generally, rare event outcomes do not provide adequate information for improvement or discrimination; however, serious reportable events that are compared to zero are appropriate outcomes for public reporting and quality improvement.  **4.** The preferred systems for grading the evidence are the Grading of Recommendations, Assessment, Development and Evaluation [(GRADE) guidelines](http://www.gradeworkinggroup.org) and/or modified GRADE.  **5.** 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 multistep process, the step with the strongest evidence for the link to the desired outcome should be selected as the focus of measurement. Note: A measure focused only on collecting PROM data is not a PRO-PM.  **6.** Measures of efficiency combine the concepts of resource use and quality (see NQF’s [Measurement Framework: Evaluating Efficiency Across Episodes of Care](http://www.qualityforum.org/Publications/2010/01/Measurement_Framework__Evaluating_Efficiency_Across_Patient-Focused_Episodes_of_Care.aspx); [AQA Principles of Efficiency Measures](http://www.aqaalliance.org/files/PrinciplesofEfficiencyMeasurementApril2006.doc)). |

**1a.1.This is a measure of**: (*should be consistent with type of measure entered in De.1*)

Outcome

Outcome: Click here to name the health outcome

Patient-reported outcome (PRO): Click here to name the PRO

*PROs include HRQoL/functional status, symptom/symptom burden, experience with care, health-related behaviors.* (*A PRO-based performance measure is not a survey instrument. Data may be collected using a survey instrument to construct a PRO measure.)*

Intermediate clinical outcome (*e.g., lab value*): Kt/V

Process: Click here to name what is being measured

Appropriate use measure: Click here to name what is being measured

Structure: Click here to name the structure

Composite: Click here to name what is being measured

**1a.2** **LOGIC MODEL** Diagram or briefly describe the steps between the healthcare structures and processes (e.g., interventions, or services) and the patient’s health outcome(s). The relationships in the diagram should be easily understood by general, non-technical audiences. Indicate the structure, process or outcome being measured.

The measure focus is measurement of spKt/V >= 1.2. This process leads to improvement in mortality as follows: Measure spKt/V--> Assess value-->Impact on mortality.

**1a.3** **Value and Meaningfulness:**  **IF** this measure is derived from patient report, provide evidence that the target population values the measured ***outcome, process, or structure*** and finds it meaningful. (Describe how and from whom their input was obtained.)

N/A

**\*\*RESPOND TO ONLY ONE SECTION BELOW -EITHER 1a.2, 1a.3 or 1a.4) \*\***

**1a.2** **FOR OUTCOME MEASURES including PATIENT REPORTED OUTCOMES - Provide empirical data demonstrating the relationship between the outcome (or PRO) to at least one healthcare structure, process, intervention, or service.**

N/A

**1a.3.****SYSTEMATIC REVIEW(SR) OF THE EVIDENCE (for intermediate outcome, PROCESS, or STRUCTURE PERFORMANCE measures, including those that are instrument-based) If the evidence is not based on a systematic review go to section 1a.4) If you wish to include more than one systematic review, add additional tables.**

**What is the source of the systematic review of the body of evidence that supports the performance measure? A systematic review is a scientific investigation that focuses on a specific question and uses explicit, prespecified scientific methods to identify, select, assess, and summarize the findings of similar but separate studies. It may include a quantitative synthesis (meta-analysis), depending on the available data. (IOM)**

X Clinical Practice Guideline recommendation (with evidence review)

☐ US Preventive Services Task Force Recommendation

☐ Other systematic review and grading of the body of evidence (*e.g., Cochrane Collaboration, AHRQ Evidence Practice Center*)

☐ Other

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| **Source of Systematic Review:**   * **Title** * **Author** * **Date** * **Citation, including page number** * **URL** | Clinical Practice Guidelines for Hemodialysis Adequacy:  KDOQI Guideline 8. Pediatric Hemodialysis Prescription and Adequacy: 2006.  http://www2.kidney.org/professionals/KDOQI/guideline\_upHD\_PD\_VA/hd\_guide8.htm |
| Quote the guideline or recommendation verbatim about the process, structure or intermediate outcome being measured. If not a guideline, summarize the conclusions from the SR. | 8.3.1 Children should receive at least the delivered dialysis dose as recommended for the adult population. (A) |
| Grade assigned to the **evidence** associated with the recommendation with the definition of the grade | N/A |
| Provide all other grades and definitions from the evidence grading system | N/A |
| Grade assigned to the **recommendation** with definition of the grade | 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.’ |
| Provide all other grades and definitions from the recommendation grading system | The rating system defined in the KDOQI Guidelines was used to grade the strength of the Guideline recommendation. KDOQI defined grades as follows:  Grade A: It is strongly recommended that clinicians routinely follow the guideline for eligible patients. There is strong evidence that the practice improves health outcomes.  Grade B: It is recommended that clinicians routinely follow the guideline for eligible patients. There is moderately strong evidence that the practice improves health outcomes.  Grade CPR: It is recommended that clinicians consider following the guideline for eligible patients. This recommendation is based on either weak evidence or on the opinions of the Work Group and reviewers that the practice might improve health outcomes. |
| Body of evidence:   * Quantity – how many studies? * Quality – what type of studies? | N/A |
| Estimates of benefit and consistency across studies | N/A |
| What harms were identified? | N/A |
| Identify any new studies conducted since the SR. Do the new studies change the conclusions from the SR? | The 2009 clinical pediatric dialysis adequacy TEP conducted a literature search, where we retrieved a total of 190 articles using several sources. First, we retrieved 79 articles using a PubMed search of articles with human subjects, published in English since January 1, 2005. The search terms were: [(pediatric OR pediatrics OR children) and (dialysis OR hemodialysis OR peritoneal dialysis) and (adequacy OR "dialysis dose" OR "dose monitoring" OR "residual renal function" OR "urea clearance" OR "solute clearance" OR "phosphate clearance" OR "amino acid clearance" OR "folate clearance" OR "Kt/V" OR "peritoneal equilibration test" OR ("ultrafiltration" and peritoneal)) and NOT (cvvhd OR "continuous veno venous" OR transplant OR "kidney transplant" OR transplantation)].  Second, we reviewed 61 citations from the Kidney Disease Outcomes Quality Initiative Guidelines on pediatric peritoneal dialysis and hemodialysis. Third, we reviewed the tables of contents of the journal Pediatric Nephrology and retrieved two articles from early on-line publishing that had not yet been included in PubMed. Finally, we reviewed the citations in 14 articles previously identified; this found an additional 65 articles for review. Duplicate articles were excluded.  A total of 124 articles were found to be relevant for measure development. Four pieces of evidence listed below [1-4] were determined to be relevant to this specific measure.  An additional literature search was conducted in May 2014 and additional evidence has been added to the list of citations [5-8].   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.   Abstract: This report summarizes morbidity in 151 patients in a cooperative trial designed to evaluate the clinical effects of different dialysis prescriptions. Four treatment groups were divided along two dimensions: dialysis treatment time (long or short), and blood urea nitrogen (BUN) concentration averaged with respect to time (TACurea) (high or low). Dietary protein was not restricted. There was no difference in mortality between the groups. Withdrawal of patients from the high-BUN groups for medical reasons was significantly greater than withdrawal from the lowBUN groups. Hospitalization was also greater in the high-BUN groups, but dialysis treatment time had no significant effects.  The data indicate that the occurrence of morbid events is affected by the dialysis prescription. Increased morbidity appears to accompany prescriptions associated with a relatively high BUN. Conversely, morbidity may be decreased by prescriptions associated with more efficient removal of urea if the dietary intake of protein and other nutrients is adequate. (N Engl J Med. 1981; 305:1176–81.)   1. 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.   BACKGROUND:   Among patients with end-stage renal disease who are treated with hemodialysis, solute clearance during dialysis and nutritional adequacy are determinants of mortality. We determined the effects of reductions in blood urea nitrogen concentrations during dialysis and changes in serum albumin concentrations, as an indicator of nutritional status, on mortality in a large group of patients treated with hemodialysis.  METHODS:  We analyzed retrospectively the demographic characteristics, mortality rate, duration of hemodialysis, serum albumin concentration, and urea reduction ratio (defined as the percent reduction in blood urea nitrogen concentration during a single dialysis treatment) in 13,473 patients treated from October 1, 1990, through March 31, 1991. The risk of death was determined as a function of the urea reduction ratio and serum albumin concentration.  RESULTS:  As compared with patients with urea reduction ratios of 65 to 69 percent, patients with values below 60 percent had a higher risk of death during follow-up (odds ratio, 1.28 for urea reduction ratios of 55 to 59 percent and 1.39 for ratios below 55 percent). Fifty-five percent of the patients had urea reduction ratios below 60 percent. The duration of dialysis was not predictive of mortality. The serum albumin concentration was a more powerful (21 times greater) predictor of death than the urea reduction ratio, and 60 percent of the patients had serum albumin concentrations predictive of an increased risk of death (values below 4.0 g per deciliter). The odds ratio for death was 1.48 for serum albumin concentrations of 3.5 to 3.9 g per deciliter and 3.13 for concentrations of 3.0 to 3.4 g per deciliter. Diabetic patients had lower serum albumin concentrations and urea reduction ratios than nondiabetic patients.  CONCLUSIONS:  Low urea reduction ratios during dialysis are associated with increased odds ratios for death. These risks are worsened by inadequate nutrition.   1. Gorman G, et al. Clinical outcomes and dialysis adequacy in adolescent hemodialysis patients. Am Journal Kidney Dis; 47: 285-93, 2006.   BACKGROUND:  The National Kidney Foundation-Kidney Disease Outcomes Quality Initiative guidelines recommend that adult hemodialysis (HD) patients receive a minimum dialysis dose by single-pooled Kt/V (spKt/V) of 1.2 or greater. There are no data to support a minimum spKt/V dose for children on HD therapy. We aim to determine the association of spKt/V with mortality and hospitalization in adolescents.  METHODS:  Clinical characteristics of adolescent HD patients aged 12 to 18 years old included in the 2000/2001 End-Stage Renal Disease Clinical Performance Measures Project were linked to US Renal Data System data from October 1, 1999, to October 15, 2001. Hospitalization risks after adjustment for time on dialysis therapy, access, hemoglobin level, albumin level, and height were determined by means of Poisson regression. spKt/V was analyzed by the adult target (< versus > or = 1.2) and by intervals.  RESULTS:  There were 613 patients with 477 patient-years of follow-up, during which there were 14 deaths and 185 hospitalizations covering 1,108 days. After adjustment, patients with an spKt/V less than 1.2 had increased hospitalization risk (1.59; 95% confidence interval, 0.98 to 2.56; P = 0.06) compared with those with an spKt/V of 1.2 or greater. Compared with patients with an spKt/V of 1.2 to 1.4, patients with an spKt/V less than 1.2 had increased adjusted risk for hospitalization (2.46; 95% confidence interval, 1.23 to 4.94; P = 0.01). Increases in spKt/V beyond 1.4 were not associated with improved outcomes.  CONCLUSION:  Applying the current adequacy guideline to adolescent HD patients is justified by the increased hospitalization risk of those who fail to attain an spKt/V of 1.2 or greater. However, attaining an spKt/V in excess of 1.4 was not associated with greater benefit.   1. Fischbach M, et al. Intensified and daily hemodialysis in children might improve statural growth. Pediatr Nephrol 21:1746–1752, 2006.   Abstract: In children conventional hemodialysis does not often improve growth. We determined linear growth in five children on in-center intensified and daily hemodialysis (IDd) regimen, with a mean age of 8 years 7 months at enrollment. Four of five were on growth hormone started for a median of 28.5 months before IDd. IDd was delivered 5 to 6 times weekly, for three hours each session. Mean follow up of IDd was 18.6 months. Dropout from IDd was kidney transplantation (n=4) or transfer to another center (n=1). IDd and free diet improved appetite, thereby protein intake, was above 2 g/kg/BW. Median weekly Kt/V(urea) was 9.1 (8.7 to 10.4). Predialysis phosphorus blood levels were higher at the start (2.04+/-0.34 mmol/L) than at end of IDd (1.39+/-0.41 mmol/L) without need for carbonate of calcium in four of five cases. During conventional dialysis ht SDS decreased from -0.8 to -1.44, which occurred predominantly before rhGH start. Conversion to IDd significantly increased growth velocity to a mean of 13 cm/year (10.3-18) with a mean change of +1.84 ht SDS/year (0.4 to 2.7). This preliminary report suggests the potential efficacy of IDd regimen in promising growth velocity, either directly from a higher dialysis dose or indirectly through an improved nutritional status.   1. Daugirdas JT. Dialysis dosing for chronic hemodialysis: beyond Kt/V. Semin Dial. 2014 Mar;27(2):98-107.   Abstract: Current views regarding hemodialysis adequacy reach beyond indices of small solute removal such as Kt/V. Nevertheless, new Kt/V-based constructs such as the standard Kt/V, which adjusts not only for dialysis frequency, but which also represents removal of sequestered solutes rather than easily removed urea, continue to be useful. The scaling of dialysis dose to measures of size other than body water results in higher recommended doses of dialysis for children, small patients, and women, compared with the current body water-based scaling approach. Aside from small solute removal, increasing weekly time on dialysis results in slower removal of fluid with better tolerance and with increased removal of phosphorus, although both salt and water and phosphorus control often respond to efforts to reduce intake. The intermediate term benefits of removing larger middle molecules such as beta-2-microglobulin appear to be modest, and the benefits of removal of protein-bound uremic toxins remain to be proved in controlled trials.   1. Kaur A, Davenport A. Hemodialysis for infants, children, and adolescents. Hemodial Int. 2014 Apr 14. doi: 10.1111/hdi.12163. [Epub ahead of print]   Abstract: Children with chronic kidney disease stage 5 requiring dialysis can be treated by peritoneal or hemodialysis. In the United Kingdom nearly twice as many children receive peritoneal dialysis compared with hemodialysis. Technical aspects of pediatric hemodialysis are challenging and include the relative size of extracorporeal circuit and child's blood volume, assessment of adequacy, technical and complications of vascular access. Alternatives to standard hospital-based hemodialysis are also increasingly available. Optimizing nutritional status with the support of specialist pediatric dietitians is key to the management of children receiving hemodialysis. The effects of chronic illness on growth and school achievement, as well as the psychological, emotional, and social development of the child should not be underestimated. This review focuses on the above elements and highlights common pediatric practice in the United Kingdom.   1. Dunne N, Campbell M, Fitzpatrick M, Callery P. Comparison of Kt/V and urea reduction ratio in measuring dialysis adequacy in paediatric haemodialysis in England.J Ren Care. 2014 Jun;40(2):117-24. doi: 10.1111/jorc.12059. Epub 2014 Mar 20.   Abstract: Background: The National Kidney Foundation-Dialysis Outcomes Quality Initiative (KDOQI) guidelines and the Renal Association recommend the use of either Kt/V or urea reduction ratio (URR) to measure haemodialysis adequacy.  Objectives: To determine the methods used to measure paediatric haemodialysis adequacy and to assess consistency between calculations of single pool Kt/V (spKt/V) and URR.  Design: A service evaluation was conducted to establish current practices in measuring dialysis adequacy. A prospective longitudinal study was conducted to compare spKt/V and URR. Participants: Thirty-two children were recruited consisting of 13 males and 19 females in five paediatric dialysis centres.  Results: Inconsistencies were reported of the method of post-urea sampling with 4 of the 10 centres using the KDOQI recommended sampling method. Five dialysis centres reported using URR and five reported using spKt/V. There were substantial differences between the two measures. Using URR suggested that up to 44% of children did not receive adequate dialysis, whereas measurement by spKt/V suggested no more than 6% of the same dialysis sessions were not adequate.  Conclusion: One standard measure should be used to assess dialysis adequacy in paediatric centres in England. KDOQI guidelines were not consistently followed in obtaining a post-urea blood sample and this procedure should be standardised.   1. Cadnapaphornchai MA, Teitelbaum I. Strategies for the preservation of residual renal function in pediatric dialysis patients. Pediatr Nephrol. 2014 May;29(5):825-36; quiz 832. doi: 10.1007/s00467-013-2554-0. Epub 2013 Jul 19.   Abstract: In adults with end-stage renal disease (ESRD), the preservation of residual renal function (RRF) has been shown to be associated with decreased mortality and improved control of complications of chronic kidney disease. However, less is known on the benefits of RRF in the pediatric dialysis population. The purpose of this article is to review the clinical significance of RRF and to discuss strategies for the preservation of RRF in children with ESRD. |

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**1a.4 OTHER SOURCE OF EVIDENCE**

*If source of evidence is NOT from a clinical practice guideline, USPSTF, or systematic review, please describe the evidence on which you are basing the performance measure.*

**1a.4.1** **Briefly SYNTHESIZE the evidence that supports the measure.** A list of references without a summary is not acceptable.

N/A

**1a.4.2 What process was used to identify the evidence?**

N/A

**1a.4.3.** **Provide the citation(s) for the evidence.**

N/A