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

**Measure Number** (*if previously endorsed*)**:** 321

**Measure Title**: Adult Kidney Disease: Peritoneal Dialysis Adequacy: Solute

**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**: 2/27/2015

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| **Instructions**  *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.*   * Respond to all questions as instructed with answers immediately following the question. 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. * Maximum of 10 pages (*incudes questions/instructions*; minimum font size 11 pt; do not change margins). ***Contact NQF staff if more pages are needed.*** * 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 Steering 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:   * Health outcome: [**3**](#Note3) a rationale supports the relationship of the health outcome to processes or structures of care. Applies to patient-reported outcomes (PRO), including health-related quality of life/functional status, symptom/symptom burden, experience with care, health-related behavior. * 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.   **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 U.S. Preventive Services Task Force (USPSTF) [grading definitions](http://www.uspreventiveservicestaskforce.org/uspstf/grades.htm) and [methods](http://www.uspreventiveservicestaskforce.org/methods.htm), or Grading of Recommendations, Assessment, Development and Evaluation [(GRADE) guidelines](http://www.gradeworkinggroup.org/publications/index.htm).  **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

Health 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*

Intermediate clinical outcome (*e.g., lab value*): Adequate dialysis dose – see 1a.2

Process: Click here to name the process

Structure: Click here to name the structure

Other: Click here to name what is being measured

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**HEALTH OUTCOME/PRO PERFORMANCE MEASURE**  *If not a health outcome or PRO, skip to* [*1a.3*](#Section1a3)

**1a.2.** **Briefly state or diagram the path between the health outcome (or PRO) and the healthcare structures, processes, interventions, or services that influence it.**

This measure captures the number of calendar months during which patients have a total Kt/V > or = 1.7 per week measured once every 4 months. This is a measurement of the adequacy of peritoneal dialysis, an intermediate clinical outcome. Adequate dialysis dose is linked to improved health outcomes such as attaining highest quality and quantity of life after onset of illness, decreasing morbidity and mortality, and increasing treatment effectiveness.

**1a.2.1.** **State the rationale supporting the relationship between the health outcome (or PRO) to at least one healthcare structure, process, intervention, or service (*i.e., influence on outcome/PRO*).**

The guideline recommendations focus on the same patient population as the measure, patients with and without residual kidney function, receiving peritoneal dialysis. The guideline states that for patients with residual kidney function, the minimal "delivered" dose of total small-solute clearance should be a total (peritoneal and kidney) Kt/Vurea of at least 1.7 per week. The guideline also states that for patients without RKF,, the minimal "delivered" dose of total small-solute clearance should be a peritoneal Kt/Vurea of at least 1.7 per week measured within the first month after starting dialysis therapy and at least once every 4 months thereafter. For feasibility purposes, the initial measurement within the first month after starting dialysis has been removed from the measure. The frequency of the measurements, however, is consistent with the guideline. Therefore, the measure is written to identify patients who have a Kt/v > or = 1.7 per week measured at least once every 4 months, consistent with the guideline recommendations, excluding the initial measurement. Adequate dialysis dose is strongly associated with better outcomes, including decreased mortality, fewer hospitalizations, fewer days in the hospital, and decreased hospital costs.

*Note: For health outcome/PRO performance measures, no further information is required; however, you may provide evidence for any of the structures, processes, interventions, or service identified above.*

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**intermediate outcome, PROCESS, or STRUCTURE PERFORMANCE measure**

**1a.3.****Briefly state or diagram the path between structure, process, intermediate outcome, and health outcomes**. Include all the steps between the measure focus and the health outcome.

**1a.3.1.** **What is the source of the systematic review of the body of evidence that supports the performance measure?**

Clinical Practice Guideline recommendation – ***complete sections*** [***1a.4***](#Section1a4)***, and*** [***1a.7***](#Section1a7)

US Preventive Services Task Force Recommendation – ***complete sections*** [***1a.5***](#Section1a5) ***and*** [***1a.7***](#Section1a7)

Other systematic review and grading of the body of evidence (*e.g., Cochrane Collaboration, AHRQ Evidence Practice Center*) – ***complete sections*** [***1a.6***](#Section1a6) ***and*** [***1a.7***](#Section1a7)

Other – ***complete section*** [***1a.8***](#Section1a8)

*Please complete the sections indicated above for the source of evidence. You may skip the sections that do not apply.*

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**1a.4. CLINICAL PRACTICE GUIDELINE RECOMMENDATION**

**1a.4.1.** **Guideline citation** (*including date*) and **URL for guideline** (*if available online*):

National Kidney Foundation. KDOQI Clinical Practice Guidelines and Clinical Practice Recommendations for 2006 Updates: Hemodialysis Adequacy, Peritoneal Dialysis Adequacy and Vascular Access. Am J Kidney Dis 48:S1-S322, 2006 (suppl 1).

<http://www.ajkd.org/article/S0272-6386%2806%2900613-5/fulltext> or

<http://www2.kidney.org/professionals/KDOQI/guideline_upHD_PD_VA/pd_guide2.htm>

**1a.4.2.** **Identify guideline recommendation number and/or page number** and **quote verbatim, the specific guideline recommendation**.

Guideline 2: For patients with RKF (considered to be significant when urine volume is >100 mL/d): the minimal “delivered” dose of total small-solute clearance should be a total (peritoneal and kidney) kt/vurea of at least 1.7 per week.

For patients without RKF (considered to be insignificant for urine volume =100 mL/d), the minimal “delivered” dose of total small-solute clearance should be a peritoneal Kt/Vurea of at least 1.7 per week measured within the first month after starting dialysis therapy and at least once every 4 months thereafter.

**1a.4.3.** **Grade assigned to the quoted recommendation with definition of the grade:**

Grade B

The strength of each guideline recommendation is based on the quality of the supporting evidence as well as additional considerations. Additional considerations, such as cost, feasibility, and incremental benefit were implicitly considered.

A It is strongly recommended that clinicians routinely follow the guideline for eligible patients. There is strong evidence that the practice improves health outcomes.

B It is recommended that clinicians routinely follow the guideline for eligible patients. There is moderately strong evidence that the practice improves health outcomes.

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.

Health outcomes are health-related events, conditions, or symptoms that can be perceived by individuals to have an important effect on their lives. Improving health outcomes implies that benefits outweigh any adverse effects.

**1a.4.4. Provide all other grades and associated definitions for recommendations in the grading system.** (*Note: If separate grades for the strength of the evidence, report them in section 1a.7.*)

**1a.4.5. Citation and URL for methodology for grading recommendations** (*if different from 1a.4.1*)**:**

**1a.4.6. If guideline is evidence-based (rather than expert opinion), are the details of the quantity, quality, and consistency of the body of evidence available (e.g., evidence tables)?**

Yes **→ *complete section*** [***1a.7***](#Section1a7)

No **→ *report on another systematic review of the evidence in sections*** [***1a.6***](#Section1a6) ***and*** [***1a.7***](#Section1a7)***; if another review does not exist, provide what is known from the guideline review of evidence in*** [***1a.7***](#Section1a7)

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**1a.5.** **UNITED STATES PREVENTIVE SERVICES TASK FORCE RECOMMENDATION**

**1a.5.1.** **Recommendation citation** (*including date*) and **URL for recommendation** (*if available online*):

**1a.5.2.** **Identify recommendation number and/or page number** and **quote verbatim, the specific recommendation**.

**1a.5.3.** **Grade assigned to the quoted recommendation with definition of the grade**:

**1a.5.4. Provide all other grades and associated definitions for recommendations in the grading system.** (*Note: the* *grading system for the evidence should be reported in section 1a.7.*)

**1a.5.5. Citation and URL for methodology for grading recommendations** (*if different from 1a.5.1*)**:**

***Complete section*** [***1a.7***](#Section1a7)

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**1a.6. OTHER SYSTEMATIC REVIEW OF THE BODY OF EVIDENCE**

**1a.6.1.** **Citation** (*including date*) and **URL** (*if available online*):

**1a.6.2.** **Citation and** **URL for methodology for evidence review and grading** (*if different from 1a.6.1*)**:**

***Complete section*** [***1a.7***](#Section1a7)

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**1a.7. FINDINGS FROM SYSTEMATIC REVIEW OF BODY OF THE EVIDENCE supporting the measure**

*If more than one systematic review of the evidence is identified above, you may choose to summarize the one (or more) for which the best information is available to provide a summary of the quantity, quality, and consistency of the body of evidence. Be sure to identify which review is the basis of the responses in this section and if more than one, provide a separate response for each review.*

**1a.7.1.** **What was the specific structure, treatment, intervention, service, or intermediate outcome addressed in the evidence review?**

**1a.7.2.** **Grade assigned for the quality of the quoted evidence with definition of the grade**: moderately strong

Strong-Evidence includes results from well-designed, well-conducted study/studies in the target population that directly assess effects on health outcomes.

Moderately Strong-Evidence is sufficient to determine effects on health outcomes in the target population, but the strength of evidence is limited by the number, quality, or consistency of the individual studies; OR evidence is from a population other than the target population, but from well-designed, well-conducted studies; OR evidence is from studies with some problems in design and/or analysis; OR evidence is from well-designed, well-conducted studies on surrogate endpoints for efficacy and/or safety in the target population.

Weak-Evidence is insufficient to assess the effects on net health outcomes because it is from studies with some problems in design and/or analysis on surrogate endpoints for efficacy and/or safety in the target population; OR the evidence is only for surrogate measures in a population other than the target population; OR the evidence is from studies that are poorly designed and/or analyzed.

**1a.7.3. Provide all other grades and associated definitions for strength of the evidence in the grading system.**

Strong-Evidence includes results from well-designed, well-conducted study/studies in the target population that directly assess effects on health outcomes.

Moderately Strong-Evidence is sufficient to determine effects on health outcomes in the target population, but the strength of evidence is limited by the number, quality, or consistency of the individual studies; OR evidence is from a population other than the target population, but from well-designed, well-conducted studies; OR evidence is from studies with some problems in design and/or analysis; OR evidence is from well-designed, well-conducted studies on surrogate endpoints for efficacy and/or safety in the target population.

Weak-Evidence is insufficient to assess the effects on net health outcomes because it is from studies with some problems in design and/or analysis on surrogate endpoints for efficacy and/or safety in the target population; OR the evidence is only for surrogate measures in a population other than the target population; OR the evidence is from studies that are poorly designed and/or analyzed.

**1a.7.4.** **What is the time period covered by the body of evidence? (*provide the date range, e.g., 1990-2010*). Date range**: 1976-2005

**QUANTITY AND QUALITY OF BODY OF EVIDENCE**

**1a.7.5.****How many and what type of study designs are included in the body of evidence**? (*e.g., 3 randomized controlled trials and 1 observational study*) A total of 2,307 citations were screened and 7 were added by the [NKF] Work Group members. There were 293 articles (263 studies in adults and 30 in children) that were potentially relevant. These articles were retrieved for full review. Of these, 101 adult articles were accepted for full data extraction by the [NKF] Work Group members. Nine articles in children were formally data extracted by a pediatric nephrologist on the Work Group. Articles in adults were randomly assigned to individual Work Group members for data extraction. Of these, 27 studies answered questions pertinent to topics chosen for systematic listing in Summary Tables.

National Kidney Foundation. KDOQI Clinical Practice Guidelines and Clinical Practice Recommendations for 2006 Updates: Hemodialysis Adequacy, Peritoneal Dialysis Adequacy and Vascular Access. Am J Kidney Dis 48:S1-S322, 2006 (suppl 1).

**1a.7.6.** **What is the overall quality of evidence across studies in the body of evidence**? (*discuss the certainty or confidence in the estimates of effect particularly in relation to study factors such as design flaws, imprecision due to small numbers, indirectness of studies to the measure focus or target population*)

Previous studies suggested that improved survival on PD therapy was associated with higher total small-molecule clearances. Extrapolations from the Canada-United States (CANUSA) Study led to the prior guidelines of a total weekly Kt/Vurea of 2.0 and creatinine clearance (CCr) of 60 L/wk/1.73 m2 for CAPD patients. Higher targets were chosen for continuous cycling PD (CCPD) and patients on APD with no daytime dwell (dry day), and, in the absence of data, based on theoretical considerations. Reanalysis of the CANUSA Study showed that RKF, rather than peritoneal clearance, was associated with improved survival. Greater urine volume was a significant and important predictor of better survival, as well. Results of this reanalysis subsequently were supported by the Adequacy of PD in Mexico (ADEMEX) Study randomized trial of CAPD patients comparing 2 levels of PD prescription. The 2 groups of patients had identical survival, indicating no benefit on survival for greater small-molecule peritoneal clearance and confirming the benefit of RKF on survival. Further support was supplied by another randomized trial of CAPD patients from Hong Kong39 comparing 3 levels of total Kt/Vurea in patients with small degrees of RKF, with the lowest group randomized to a total Kt/Vurea of 1.5 to 1.7, with no difference in survival.

There are only 2 randomized trials of dialysis dose in PD patients. The study designs were different in that the ADEMEX Study targeted a higher level of peritoneal clearance (not quite achieved), whereas the Hong Kong trial targeted 3 levels of total Kt/Vurea, combining kidney and peritoneal clearance to achieve this and adjusting the PD prescription to stay within the indicated goal. Each study had a homogeneous ethnic population (Mexican and Chinese, respectively). Therefore, the ability to apply these results to different ethnic groups and more culturally heterogeneous populations is limited and is the reason that the evidence is listed as moderate, rather than strong. Of particular concern is the variability in adherence to home prescription in other cultures in which adherence was shown to be problematic in some patients.

**ESTIMATES OF BENEFIT AND CONSISTENCY ACROSS STUDIES IN BODY OF EVIDENCE**

**1a.7.7.** **What are the estimates of benefit—magnitude and direction of effect on outcome(s) across studies in the body of evidence**? (*e.g., ranges of percentages or odds ratios for improvement/ decline across studies, results of meta-analysis, and statistical significance*)

Results of the ADEMEX Study are consistent with a subsequent randomized trial in Hong Kong comparing total Kt/Vurea values of 1.5 to 1.7, 1.7 to 2.0, and greater than 2.0 in CAPD patients. There were no differences in patient survival in the 3 groups. All patients at the start of the study had residual kidney Kt/Vurea of 1.0 or less, ensuring minimal RKF. Baseline residual GFRs (rGFRs) were 2.38, 2.48, and 2.64 mL/min/1.73 m2, respectively (representing kidney Kt/Vurea s of 0.44, 0.46, and 0.49 in the 3 groups, respectively; not a significant difference). Average BMI was 22 kg/m2, somewhat smaller than that of patients in the ADEMEX Study. The usual prescription was three 2-L exchanges per day, as opposed to four 2-L exchanges in the control arm of the ADEMEX Study. During the course of the 2-year study, PD prescription was adjusted up or down as RKF changed to stay within the randomized total Kt/Vurea category. By the end of the study, residual kidney Kt/Vurea was at or less than 0.1 in all 3 categories. Dialysis adequacy was assessed every 6 months. Results of these 2 important studies highlight the need to look at factors other than small-molecule clearance to improve survival in PD patients because peritoneal small-molecule clearance was not a predictor of survival, hospitalization, or nutritional state.

Observational studies support the findings of these 2 randomized trials, indicating that RKF (in those with RKF), rather than level of peritoneal small-molecule clearance, predicts survival, as well as QOL. In a large group of US PD patients (1,603 patients), age and serum albumin level were predictors of death, as was RKF; however, peritoneal clearance was not. Another study of 763 patients found that neither peritoneal Kt/Vurea nor peritoneal CCr was predictive of 1-year mortality. This population consisted of 53% CAPD and 34% CCPD patients; the rest were on both modalities during the 6-month study period or information was missing. In a longitudinal study of 412 adult PD patients (mean age, 52 years; 66.3% men, 15.3% with diabetic nephropathy), survival was predicted by GFR (RR, 0.88; 95% confidence interval [CI], 0.79 to 0.99; P = 0.039) and not peritoneal CCr. Comorbidity, albumin level at baseline, and age also were predictive of survival. Transport status was not a predictor of survival in this cohort. Kidney rGFR also was associated with multiple measures of better QOL, in contrast to peritoneal clearance, which was not associated with any component of QOL. In yet another study, transport status was not associated with survival, but survivors had significantly more residual function than those who did not survive (4.5 versus 2.8 mL/min/1.73 m2). Low initial RKF was associated with greater C-reactive protein (CRP) levels, indicating a relationship between inflammation and loss of RKF.

To summarize, since the last guidelines were published, 2 randomized trials examining different levels of small-molecule clearance have been done in CAPD patients, showing no benefit of the higher small-molecule clearances on patient survival, nutritional status, hospitalization, or QOL. Emerging data suggest that the focus to improve survival in PD patients should be on preserving [Residual Kidney Function] RKF, controlling volume overload (and thus blood pressure), treating metabolic acidosis, and perhaps use of protein supplements. Therefore, the minimal target is changed to a minimum Kt/Vurea of 1.7 per week, but careful attention must be paid to adherence to the prescription. The [NKF] Work Group wishes to emphasize that this minimal target should not be interpreted as an average value for a program, but that each patient should have a total Kt/Vurea at 1.7 or higher.

**1a.7.8.** **What harms were studied and how do they affect the net benefit (benefits over harms)?**

The prescribed dose of PD, as is true of HD, is not invariably the delivered dose. Patients adjust the timing of exchanges, eliminate exchanges, and change the dextrose of the dialysis solution, resulting in variations in ultrafiltration that, in turn, affect small-molecule clearance. Patients are responsible for their dialysis delivery, yet depression is common in PD patients, which may impact on adherence.75,76 Close attention must be paid to the patient´s ability to perform (mentally and physically) his or her dialysis.

Furthermore, RKF does not remain stable. It is affected by volume status and tends to decrease over time. Therefore, if including residual kidney clearance as part of total Kt/Vurea, the measured dose of Kt/Vurea may not precisely reflect the delivered dose of Kt/Vurea, which will be less in some cases. This means that the clinician should err on the side of a higher prescribed dose when possible.

Implementation of the goal of euvolemia in PD patients involves close monitoring of urine volume, ultrafiltration, and physical examination, including blood pressure. Both home records and in-center measurements are needed. Frequent contact with the patient to supervise the use of the appropriate dialysis dextrose solution is necessary. The use of loop diuretics may be indicated to increase urine volume as appropriate (discussed later). “Negative” ultrafiltration with the long exchange should be avoided by adjusting the prescription and dialysate dextrose solution.

**UPDATE TO THE SYSTEMATIC REVIEW(S) OF THE BODY OF EVIDENCE**

**1a.7.9.** **If new studies have been conducted since the systematic review of the body of evidence, provide for each new study: 1) citation, 2) description, 3) results, 4) impact on conclusions of systematic review**.

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**1a.8 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.8.1** **What process was used to identify the evidence?**

**1a.8.2.** **Provide the citation and summary for each piece of evidence.**