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

**Measure Number** (*if previously endorsed*)**:** 0318

**Measure Title**: Delivered Dose of Peritoneal Dialysis Above Minimum

**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 the process of measuring peritoneal dialysis adequacy every four months for ESRD dialysis patients to assess adequate dialysis. This leads to improvement in mortality as follows: Measure PD adequacy-->Assess value-->Identify problem-->Identify treatment options-->Administer the appropriate treatment-->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** | 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.kidney.org/professionals/KDOQI/guidelines\_commentaries |
| 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. | Adult Kt/V target:  GUIDELINE 2. PERITONEAL DIALYSIS SOLUTE CLEARANCE TARGETS AND MEASUREMENTS  Data from RCTs suggested that the minimally acceptable small-solute clearance for PD is less than the prior recommended level of a weekly Kt/Vurea of 2.0. Furthermore, increasing evidence indicates the importance of RKF as opposed to peritoneal small-solute clearance with respect to predicting patient survival. Therefore, prior targets have been revised as indicated next. 2.1 For patients with RKF (considered to be significant when urine volume is > 100 mL/d): 2.1.1 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. (B)  2.1.2 Total solute clearance (residual kidney and peritoneal, in terms of Kt/Vurea) should be measured within the first month after initiating dialysis therapy and at least once every 4 months thereafter. (B)  2.1.3 If the patient has greater than 100 mL/d of residual kidney volume and residual kidney clearance is being considered as part of the patient ´s total weekly solute clearance goal, a 24-hour urine collection for urine volume and solute clearance determinations should be obtained at a minimum of every 2 months. (B) 2.2 For patients without RKF (considered insignificant when urine volume is =100 mL/d):  2.2.1 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. (B) |
| 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 | The guidelines for adult patients were graded B. 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. |
| 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? | 20 studies, ranging from 1998-2004  The KDOQI panel noted that the body of evidence shows a correlation between total solute clearance for urea and patient mortality and morbidity. Thus, this evidence supports that the delivered dose of dialysis should be measured frequently for assessment of adequate treatment, and treatment should be set accordingly. In particular, of the 20 studies considered in the body of evidence, the results from two randomized clinical trials were used to justify the KDOQI guidelines [2,3]. The results from additional observational studies also supported the KDOQI recommendations [see, e.g. 1,6].   1. Bargman JM, Thorpe KE, Churchill DN: Relative contribution of residual renal function and peritoneal clearance to adequacy of dialysis: A reanalysis of the CANUSA Study. J Am Soc Nephrol 12:2158-2162, 2001 2. Paniagua R, Amato D, Vonesh E, et al: Effects of increased peritoneal clearances on mortality rates in peritoneal dialysis: ADEMEX, a prospective, randomized, controlled trial. J Am Soc Nephrol 13:1307-1320, 2002 3. Lo WK, Ho YW, Li CS, et al: Effect of Kt/V on survival and clinical outcome in CAPD patients in a randomized prospective study. Kidney Int 64:649-656, 2003 4. Szeto CC, Wong TY, Leung CB, et al: Importance of dialysis adequacy in mortality and morbidity of Chinese CAPD patients. Kidney Int 58:400-407, 2000 5. Diaz-Buxo JA, Lowrie EG, Lew NL, Zhang SM, Zhu X, Lazarus JM: Associates of mortality among peritoneal dialysis patients with special reference to peritoneal transport rates and solute clearance. Am J Kidney Dis 33:523-534, 1999 6. Rocco MV, Frankenfield DL, Prowant B, Frederick P, Flanigan MJ: Risk factors for early mortality in U.S. peritoneal dialysis patients: Impact of residual renal function. Perit Dial Int 2002 22:371-379 7. Termorshuizen F, Korevaar JC, Dekker FW, van Manen JG, Boeschoten EW, Krediet RT: The relative importance of residual renal function compared with peritoneal clearance for patient survival and quality of life: An analysis of the Netherlands Cooperative Study on the Adequacy of Dialysis (NECOSAD)-2. Am J Kidney Dis 41:1293-1302, 2003 8. Chung SH, Heimburger O, Stenvinkel P, Qureshi AR, Lindholm B: Association between residual renal function, inflammation and patient survival in new peritoneal dialysis patients. Nephrol Dial Transplant 18:590-597, 2003 9. Jager KJ, Merkus MP, Dekker FW, et al: Mortality and technique failure in patients starting chronic peritoneal dialysis: Results of The Netherlands Cooperative Study on the Adequacy of Dialysis. NECOSAD Study roup. Kidney Int 55:1476-1485, 1999 10. Ates K, Nergizoglu G, Keven K, et al: Effect of fluid and sodium removal on mortality in peritoneal dialysis patients. Kidney Int 60:767-776, 2001 11. Wang AY, Wang M, Woo J, et al: Inflammation, residual kidney function, and cardiac hypertrophy are interrelated and combine adversely to enhance mortality and cardiovascular death risk of peritoneal dialysis patients. J Am Soc Nephrol 15:2186-2194, 2004 12. Szeto CC, Wong TY, Chow KM, Leung CB, Law MC, Li PK: Independent effects of renal and peritoneal clearances on the mortality of peritoneal dialysis patients. Perit Dial Int 24:58-64, 2004 13. Szeto CC, Wong TY, Chow KM, et al: Impact of dialysis adequacy on the mortality and morbidity of anuric Chinese patients receiving continuous ambulatory peritoneal dialysis. J Am Soc Nephrol 12:355-360, 2001 14. Bhaskaran S, Schaubel DE, Jassal SV, et al: The effect of small solute clearances on survival of anuric peritoneal dialysis patients. Perit Dial Int 20:181-187, 2000 15. Rocco M, Soucie JM, Pastan S, McClellan WM: Peritoneal dialysis adequacy and risk of death. Kidney Int 58:446-457, 2000 16. Lo WK, Tong KL, Li CS, et al: Relationship between adequacy of dialysis and nutritional status, and their impact on patient survival on CAPD in Hong Kong. Perit Dial Int 21:441-447, 2001 17. Davies SJ, Phillips L, Russell GI: Peritoneal solute transport predicts survival on CAPD independently of residual renal function. Nephrol Dial Transplant 13:962-968, 1998 18. Perez RA, Blake PG, Spanner E, et al: High creatinine excretion ratio predicts a good outcome in peritoneal dialysis patients. Am J Kidney Dis 36:362-367, 2000 19. Park HC, Kang SW, Choi KH, Ha SK, Han DS, Lee HY: Clinical outcome in continuous ambulatory peritoneal dialysis patients is not influenced by high peritoneal transport status. Perit Dial Int 21:S80-S85, 2001 (suppl 3) 20. Aslam N, Bernardini J, Fried L, Piraino B: Peritoneal dialysis clearance can replace residual renal function. Perit Dial Int 21:263- 268, 2001 |
| Estimates of benefit and consistency across studies | In the adult population, among the studies showing any improvement in mortality in high total clearance versus low total clearance, relative risks ranged from 0.6 to 0.99. In one study, Kt/V was measured as continuous and found a relative risk of 0.94 per 0.1 mL/min increase in Kt/V (95% CI = 0.88, 1.02). The majority of the studies showed a benefit of higher total clearance in PD patients. |
| What harms were identified? | As described above in 1a.7.7, the majority of studies showed a benefit of higher total clearance in PD patients. Furthermore, there is little or no potential harm in assessing total urea Kt/V for PD patients. |
| Identify any new studies conducted since the SR. Do the new studies change the conclusions from the SR? | In May 2014, an additional literature search was performed. Additional pieces of evidence supporting the relationship between PD clearance and outcomes are included in the citations below as a result of that search.   1. Krediet RT1, Struijk DG. Peritoneal changes in patients on long-term peritoneal dialysis. Nat Rev Nephrol. 2013 Jul;9(7):419-29. doi: 10.1038/nrneph.2013.99. Epub 2013 May 14.   Abstract: Long-term peritoneal dialysis can lead to morphological and functional changes in the peritoneum. Although the range of morphological alterations is known for the peritoneal dialysis population as a whole, these changes will not occur in every patient in the same sequence and to the same extent. Longitudinal studies are therefore required to help identify which patients might develop the changes. Although longitudinal studies using peritoneal biopsies are not possible, analyses of peritoneal effluent biomarkers that represent morphological alterations could provide insight. Longitudinal studies on peritoneal transport have been performed, but follow-up has often been too short and an insufficient number of parameters have been investigated. This Review will firstly describe peritoneal morphology and structure and will then focus on peritoneal effluent biomarkers and their changes over time. Net ultrafiltration will also be discussed together with the transport of small solutes. Data on the peritoneal transport of serum proteins show that serum protein levels do not increase to the same extent as levels of small solutes with long-term peritoneal dialysis. Early alterations in peritoneal transport must be distinguished from alterations that only develop with long-term peritoneal dialysis. Early alterations are related to vasoactive mediators, whereas later alterations are related to neoangiogenesis and fibrosis. Modern peritoneal dialysis should focus on the early detection of long-term membrane alterations by biomarkers--such as cancer antigen 125, interleukin-6 and plasminogen activator inhibitor 1--and the improved assessment of peritoneal transport.   1. Fissell R1, Schulman G, Pfister M, Zhang L, Hung AM. Novel dialysis modalities: do we need new metrics to optimize treatment? J Clin Pharmacol. 2012 Jan;52(1 Suppl):72S-8S. doi: 10.1177/0091270011414576.   Abstract: Delivered dose of hemodialysis has long been an important predictor of mortality. The limitations of conventional hemodialysis treatments have led to a renewed interest in more frequent and longer hemodialysis treatments. As alternative hemodialysis schedules have become more prevalent, a need for modified metrics to measure adequacy has emerged. In addition, there is an interest in finding measures of hemodialysis adequacy that are more reliable in certain subgroups of patients, such as women, ethnic minority groups, or people with small body size. Finally, extended hemodialysis schedules suggest a need for metrics that can measure the clearance of solutes other than urea, such as middle-size molecules, and solutes for which clearance depends on intercompartmental transport across membranes. New metrics to quantify clearance in extended and alternate hemodialysis schedules are needed. As new metrics are developed, it is anticipated that they will also contribute to more accurate assessments of associations between clinical outcomes and delivered dose of dialysis in more intensive, nontraditional hemodialysis schedules. This review provides a historical prospective of dialysis dose and adequacy and describes the need for new metrics from both solute type and dialysis dose prospective as alternative hemodialysis schedules have emerged and become more prevalent. |

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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