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

**Measure Number** (*if previously endorsed*)**:** 0249

**Measure Title**: Delivered Dose of Hemodialysis 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 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** | National Kidney Foundation. KDOQI Clinical Practice Guidelines and Clinical Practice Recommendations for Hemodialysis Adequacy, Update 2006. http://www.kidney.org/professionals/KDOQI/guidelines\_commentaries  National Kidney Foundation. KDOQI clinical practice guideline for hemodialysis adequacy: 2015 update. Am J Kidney Dis. 2015;66(5):884-930. 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. | 4.1 The minimally adequate dose of HD given 3 times per week to patients with Kr less than 2 mL/min/1.73 m2 should be an spKt/V (excluding RKF) of 1.2 per dialysis session. (A)  We recommend a target single pool Kt/V (spKt/V) of 1.4 per hemodialysis session for patients treated thrice weekly, with a minimum delivered spKt/V of 1.2. (1B) |
| Grade assigned to the **evidence** associated with the recommendation with the definition of the grade | 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: Moderate quality of evidence. The true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different. |
| Provide all other grades and definitions from the evidence 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.  The rating system defined in the KDOQI Guidelines was used to grade the strength of the Guideline recommendation. KDOQI defined grades as follows:  A: High quality of evidence. We are confident that the true effect lies close to that of the estimate of the effect.  B: Moderate quality of evidence. The true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different.  C: Low quality of evidence. The true effect may be substantially different from the estimate of the effect.  D: Very low quality of evidence. The estimate of effect is very uncertain and often will be far from the truth. |
| Grade assigned to the **recommendation** with definition of the grade | Level 1 (strong recommendation): “We Recommend”.  Implications   * Patients: Most people in your situation would want the recommended course of action and only a small proportion would not. * Clinicians: Most patients should receive the recommended course of action. * Policy: The recommendation can be adopted as policy in most situations. |
| Provide all other grades and definitions from the recommendation grading system | Level 2 (conditional recommendation/suggestion): “We Suggest”. Implications:   * Patients: The majority of people in your situation would want the recommended course of action, but many would not. * Clinicians: Different choices will be appropriate for different patients. Each patient needs help to arrive at a management   decision consistent with her or his values and preferences.   * Policy: The recommendation is likely to require substantial debate and involvement of stakeholders before policy can be determined. |
| Body of evidence:   * Quantity – how many studies? * Quality – what type of studies? | The 2015 K/DOQI guidelines are essentially unchanged with respect to small solute clearance targets using the urea kinetic approach for a single dialysis session in the setting of thrice weekly hemodialysis. The literature reviewed in preparation for these guidelines include clinical trials and observational studies published between 2000 and March 2014. The body of evidence showed a correlation between delivered dose of HD and patient mortality and morbidity. Thus, this evidence directly supports this measure. Of the 11 studies, 5 measured dialysis dose using spKt/v [1,3,8,9,10], and 3 used URR[4,5,7]. The remaining studies used eKt/V [2,6]. Among the studies using spKt/V, one study was a randomized clinical trial (HEMO study) with 1846 patients, one was a prospective study with 740 patients, and the remaining were retrospective cohort studies with sample sizes of 1771 and 1151. Two of these studies found a significant improvement in mortality with increasing dose of spKt/V. The remaining study compared higher doses of spKt/v to the standard dose (spKt/V =1.2) and found higher doses did not improvement in mortality compared to the standard dose. Of the three studies measuring URR, one study found a significant association between increased URR and lower mortality among all patients, one also found higher URR was associated with lower mortality but only among women, and one study found no significant association between URR and mortality.   1. Eknoyan G, Beck GJ, Cheung AK, et al: Effect of dialysis dose and membrane flux in maintenance hemodialysis. N Engl J Med347:2010-2019, 2002. 2. Depner T, Daugirdas J, Greene T, et al: Dialysis dose and the effect of gender and body size on outcome in the HEMO Study. Kidney Int 65:1386-1394, 2004. 3. Termorshuizen F, Dekker FW, van Manen JG, Korevaar JC, Boeschoten EW, Krediet RT: Relative contribution of residual renal function and different measures of adequacy to survival in hemodialysis patients: An analysis of the Netherlands Cooperative Study on the Adequacy of Dialysis (NECOSAD)-2. J Am Soc Nephrol 15:1061-1070, 2004. 4. Port FK, Wolfe RA, Hulbert-Shearon TE, McCullough KP, Ashby VB, Held PJ: High dialysis dose is associated with lower mortality among women but not among men. Am J Kidney Dis 43:1014-1023, 2004. 5. 5.Port FK, Ashby VB, Dhingra RK, Roys EC, Wolfe RA: Dialysis dose and body mass index are strongly associated with survival in hemodialysis patients. J Am Soc Nephrol 13:1061-1066, 2002. 6. Wolfe RA, Ashby VB, Daugirdas JT, Agodoa LY, Jones CA, Port FK: Body size, dose of hemodialysis, and mortality. Am J Kidney Dis 35:80-88, 2000. 7. Chertow GM, Owen WF, Lazarus JM, Lew NL, Lowrie EG: Exploring the reverse J-shaped curve between urea reduction ratio and mortality. Kidney Int 56:1872-1878, 1999. 8. Leypoldt JK, Cheung AK, Carroll CE, et al: Effect of dialysis membranes and middle molecule removal on chronic hemodialysis patient survival. Am J Kidney Dis 33:349-355, 1999. 9. Salahudeen AK, Dykes P, May W: Risk factors for higher mortality at the highest levels of spKt/V in hemodialysis patients.Nephrol Dial Transplant 18:1339-1344, 2003. 10. Woods HF, Nandakumar M: Improved outcome for haemodialysis patients treated with high-flux membranes. Nephrol Dial Transplant 15:S36-S42, 2000 (suppl 1). |
| Estimates of benefit and consistency across studies | Among the studies showing a significant improvement in mortality with increasing dose of spKt/V, relative risks (RR) were presented as spKt/V per increase of 1 unit and spKt/V per 0.1 unit, where spKt/V was analyzed as a continuous measure. The RR per 1 unit increase in spKt/V was 0.76 (95% CI: 0.64, 0.92; p=0.004) [3], and per 0.1 unit increase in spKt/V was 0.95; p<0.05 (no CI given) [8]. The HEMO trial found no significant difference in mortality among patients in the high dose group, with mean = 1.56 and SD=0.09, compared to the low dose group with mean=1.16 and SD=0.08 (RR=0.96; 95% CI: 0.84, 1.10) [1], thus supporting the current target spKt/V of 1.2. However, a subgroup analysis of the HEMO study [2] showed that survival rates in women randomized to the higher dose group were higher than women in the lower dose group (relative risk 0.81; p = 0.02) and this association persisted after adjusting for body size. In the remaining study, findings showed patients receiving the highest dialysis dose (spKt/V>2.4) compared to the standard dose group (spKt/V 1.2-1.3) had an increased risk of mortality (RR=2.5; p<0.05), although this may be suggestive of confounding by indication. No other significant associations between dose groups were found in this study [9]. All but one study showed a benefit for a minimum dose of dialysis when measured as spKt/V. |
| What harms were identified? | Studies evaluating higher doses of dialysis adequacy did not demonstrate additional benefit at spKt/V doses higher than the current target of 1.2. The increase in mortality at the highest dialysis dose is thought to be due to confounding by indication and does not suggest that higher dialysis dose is associated with increased mortality. |
| Identify any new studies conducted since the SR. Do the new studies change the conclusions from the SR? | N/A |

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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