Peer Reviewed Journal Article Requirement Template

Section 101(c)(1) of the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA)requires submission of new measures for publication in applicable specialty-appropriate, peer-reviewed journals prior to implementing in the Merit-based Incentive Payment System (MIPS).These measures will be submitted by the Centers for Medicare & Medicaid Services (CMS), to a journal(s) before including any new measure in the final list of annual clinical quality measures (CQM) under MIPS. The measure owner shall provide the required information for article submission under the MACRA per CMS “Call for Measures” submission process.

Measure owners submitting measures into JIRA1 must complete the required information by the Call for Measures deadline. Some of the information requested below may be listed in specific fields in the JIRA tool, however to ensure that CMS has all of the necessary information and to avoid delays in the evaluation of your submission, please fully complete this form as an attached Word document in JIRA. The information in JIRA must be consistent with the information below. This includes, but is not limited to:

***Measure Title: Hemodialysis Vascular Access: Practitioner Level Long-term Catheter Rate***

***Domain: Effective Clinical Care
Meaningful Measure Area (MMA): Management of Chronic Conditions***

**Measure Owner:** *Centers for Medicare and Medicaid Services*

**Measure Developer:** *University of Michigan Kidney Epidemiology and Cost Center*

**Description:** Percentage of adult hemodialysis patient-months using a catheter continuously for three months or longer for vascular access attributable to an individual practitioner or group practice.

1. **Statement**
* *Background (Why is this measure important?)*Based upon data from the CMS Fistula First/Catheter Last initiative, a gradual trend towards lower catheter use has been observed among prevalent maintenance HD patients in the US, declining from approximately 28% in 2006 to approximately 18% by August 2015. Furthermore, the percentage of maintenance HD patients using a catheter for at least three months has declined as well over this time period from nearly 12% to 10.8%. This implies that continued monitoring of chronic catheter use is needed to sustain this trend. Addition of practitioner level measures may create opportunities for further improvement of this important quality metric.

The 12 studies listed below highlight the core benefits associated with using an AV fistula or graft such as reduced mortality and morbidity relative to using a tunneled catheter. Specifically, AV fistula have:

* Lowest Cost1-3: Compared to catheters, Medicare expenditures for AVF are approximately $17,000 less per person per year.
* Lowest rates of infection: AV fistula have the lowest rates of infection followed by AV grafts and then tunneled dialysis catheters4. Vascular access infections are common, and represent the second most common cause of death for patients receiving hemodialysis.5
* Lowest mortality and hospitalization: Patients using catheters (RR=2.3) and grafts (RR=1.47) have a greater mortality risk than patients dialyzed with fistulae6-9. Other studies have also found that use of fistulae reduces mortality and morbidity10-12 compared to AV grafts or catheters.

References:

1. Mehta S: Statistical summary of clinical results of vascular access procedures for haemodialysis, in Sommer BG, Henry ML (eds): Vascular Access for Hemodialysis-II (ed 2). Chicago, IL, Gore, 1991, pp 145-157
2. The Cost Effectiveness of Alternative Types of Vascular access and the Economic Cost of ESRD. Bethesda, MD, National Institutes of Health, National Institute of Diabetes and Digestive and Kidney Diseases, 1995, pp 139-157
3. Eggers P, Milam R: Trends in vascular access procedures and expenditures in Medicare’s ESRD program, in Henry ML (ed): Vascular Access for Hemodialysis-VII. Chicago, IL, Gore, 2001, pp 133-143
4. Nassar GM, Ayus JC: Infectious complications of the hemodialysis access. Kidney Int 60:1-13, 2001
5. Gulati S, Sahu KM, Avula S, Sharma RK, Ayyagiri A, Pandey CM: Role of vascular access as a risk factor for infections in hemodialysis. Ren Fail 25:967-973, 2003
6. Dhingra RK, Young EW, Hulbert-Shearon TE, Leavey SF, Port FK: Type of vascular access and mortality in U.S. hemodialysis patients. Kidney Int 60:1443-1451, 2001
7. Woods JD, Port FK: The impact of vascular access for haemodialysis on patient morbidity and mortality. Nephrol Dial Transplant 12:657-659, 1997
8. Xue JL, Dahl D, Ebben JP, Collins AJ: The association of initial hemodialysis access type with mortality outcomes in elderly Medicare ESRD patients. Am J Kidney Dis 42:1013-1019, 2003
9. Polkinghorne KR, McDonald SP, Atkins RC, Kerr PG: Vascular access and all-cause mortality: A propensity score analysis. J Am Soc Nephrol 15:477-486, 2004
10. Huber TS, Carter JW, Carter RL, Seeger JM: Patency of autogenous and polytetrafluoroethylene upper extremity arteriovenous hemodialysis accesses: A systematic review. J Vasc Surg 38(5):1005-11, 2003
11. Perera GB, Mueller MP, Kubaska SM, Wilson SE, Lawrence PF, Fujitani RM: Superiority of autogenous arteriovenous hemodialysis access: Maintenance of function with fewer secondary interventions. Ann Vasc Surg 18:66-73, 2004
12. Pisoni RL, Young EW, Dykstra DM, et al: Vascular access use in Europe and the United States: Results from the DOPPS. Kidney Int 61:305-316, 2002
* *Environmental Scan (Are there existing measures in this area?)*
Two facility level metrics:

	+ #2977 Hemodialysis Vascular Access: Standardized Fistula Rate
	+ #2978 Hemodialysis Vascular Access: Long-term Catheter Rate
1. **Gap Analysis**
* *Provide Evidence for the Measure (What are the gaps and opportunities to improve care?)*

Analysis of CROWNWeb data from January 2016- December 2016 indicated the physican-level mean percentage of patient-months with a long-term catheter was 9.7% (SD=9.0%). Distribution: Min=0%, 1st quartile=4.5%, median=8.3%, 3rd quartile=12.7%, Max=100%.

* *Expected Outcome (Patient care/patient health improvements, cost savings)*Encourage reduction in catheter use
* *Recommendation for the Measure (Is it based on a study, consensus opinion, USPSTF recommendation etc.?)*

GUIDELINE 2. SELECTION AND PLACEMENT OF HEMODIALYSIS ACCESS

A structured approach to the type and location of long-term HD accesses should help optimize access survival and minimize complications. Options for fistula placement should be considered first, followed by prosthetic grafts if fistula placement is not possible. Catheters should be avoided for HD and used only when other options listed are not available.

2.1 The order of preference for placement of fistulae in patients with kidney failure who choose HD as their initial mode of KRT should be (in descending order of preference):

2.1.1 Preferred: Fistulae. (B)

2.1.2 Acceptable: AVG of synthetic or biological material. (B)

2.1.3 Avoid if possible: Long-term catheters. (B)

2.1.4 Patients should be considered for construction of a primary fistula after failure of every dialysis AV access. (B)

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.kidney.org/professionals/KDOQI/guidelines_commentaries>

1. **Reliability/Validity**
2. *What testing has been performed at the clinician level? Please provide testing results including the N value, Bonnie test case results, correlation coefficient and any other pertinent information or values to be considered.*
* *Reliability Testing Results:*Patients on both home and in-center hemodialysis during the last HD treatment of the month from January 2016-December 2016 were included in the analyses. The number of clinicians per month ranged from 7,921-8,058 and the total number of patient-months ranged from 249,965- 256,693.

The IUR is 0.602.The IUR indicates that 60.2% of the variation in the annual long-term catheter rate can be attributed to between-practitioner differences in performance (signal) and about 39.8% to the within-practitioner variation (noise). This value of IUR implies a moderate degree of reliability.

* *Validity Testing Results, clinician sites:*Patients on both home and in-center hemodialysis during the last HD treatment of the month from January 2016-December 2016 were included in the analyses. The number of clinicians per month ranged from 7,921-8,058 and the total number of patient-months ranged from 249,965- 256,693.

Validity was assessed using the trend test to measure the association between patient level number of catheter months occurred in January-March 2016 and mortality in the following 6 months (April-September 2016). Mortality in the chronic dialysis population has been associated with presence of long-term catheter use in dialysis facility level analyses performed for NQF measure submission and in numerous published studies. The association has construct validity as presence of a long-term catheter has known complications that can cause death, including septicemia and pulmonary embolism. Percentages of death were calculated in each category of patient level catheter months (i.e. 0,1,2,3 months).

Percentages of death are 6.9%, 11.1%, 11.9%, and 11.8% for patients with 0, 1, 2, and 3 months of catheter use respectively.

* *Exclusion frequency:*

Table 1: Percent of patient-months at risk excluded

|  |  |  |  |
| --- | --- | --- | --- |
| **Year** | **Before Exclusion** | **After Exclusion** | **Percent** |
| 2016 | 3,082,045 | 3,035,130 | 1.52% |

Table 2: Number and percent of unique patients excluded

|  |  |  |  |
| --- | --- | --- | --- |
| **Year** | **Before Exclusion**  | **After Exclusion**  | **Percent** |
| 2016 | 343,840 | 338,718 | 1.49% |

Table 3: Distribution of performance scores before and after the exclusion

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Catheter Rate** | **N** | **Mean** | **Standard Deviation** | **Minimum** | **Maximum** |
| Before exclusion | 8037 | 10.4% | 6.5% | 0.0% | 66.2% |
| After exclusion | 8037 | 9.7% | 6.3% | 0.0% | 66.2% |

* *What were the minimum sample sizes used for reliability results?*Practitioners with <11 eligible patients were excluded from the IUR calculation.
1. *Other Information:*
* *Is it risk adjusted? If so, how?*

No Risk Adjustment

* + *What benchmarking information is available?*None
	+ *Collection Type: Specify the data collection type.*Data is obtained from Medicare claims and CROWNWeb
1. **Endorsement**
* *Provide NQF endorsement status (and ID) and/or other endorsing body (If measure is only endorsed for paper records, please note endorsement for only the data source being submitted)*Not endorsed; submission planned in 2020
1. **Summary**
* *Alignment with CMS Meaningful Measures Initiative or MACRA (If applicable)*This measure falls into the Management of Chronic Conditions goal of CMS’s Meaningful Measures Initiative.
* *Importance to MIPS or other CMS programs*This measure will incentivize clinicians to evaluate their patients’ vascular access status and will potentially reduce infection, mortality and hospitalization rates.
* *Rationale: Use of measure for inclusion in program (specialty society, regional collaborative, other)*This measure is in support of the KDOQI guidelines cited above. The logic model is as follows: measure long term catheter rate-> Assess value ->Identify patients who do not have an AV Fistula or AV graft->Evaluation for an AV fistula or graft by a qualified dialysis vascular access provider->Increase Fistula/Graft Rate ->Lower catheter rate->Lower patient mortality.
* *Public reporting (if applicable)*
Because this measure has not been implemented yet, it is not publicly reported.
* *Preferable relevant Peer-Reviewed Journal for publication*

Journal of the American Society of Nephrology