NATIONAL QUALITY FORUM

MEASURE WORKSHEET

This document summarizes the evaluation of the measure as it progresses through NQF's Consensus Development Process (CDP). The information submitted by measure developers/stewards is included after the Brief Measure Information, Preliminary Analysis, and Pre-meeting Public and Member Comments sections.

To navigate the links in the worksheet: Ctrl + click link to go to the link; ALT + LEFT ARROW to return

Brief Measure Information

NQF #: 2978

Corresponding Measures:

De.2. Measure Title: Hemodialysis Vascular Access: Long-term Catheter Rate

Co.1.1. Measure Steward: Centers for Medicare & Medicaid Services

De.3. Brief Description of Measure: Percentage of adult hemodialysis patient-months using a catheter continuously for three months or longer for vascular access.

1b.1. Developer Rationale: According to data from the USRDS (based on CMS Fistula First and CROWNWeb data sources; USRDS 2018), in 2016, 80% of patients started hemodialysis with a catheter; and 69% of patients were still using catheters 90-days after starting chronic hemodialysis. Despite the persistent high use of catheters at dialysis initiation, a gradual trend towards lower long-term catheter use has been observed among prevalent maintenance HD patients in the US, declining from approximately 13.5% in 2003 to approximately 9.4% by December 2015. Additional reductions in the long-term catheter use has been achieved with rates for prevalent dialysis patients declining to 8.1% in May 2017.

Continued monitoring of chronic catheter use is needed to sustain this trend and decrease chronic catheter use. This measure is intended to be jointly reported with the Hemodialysis Vascular Access- Standardized Fistula Rate. These two vascular access quality measures, when used together, consider Arterial Venous (AV) fistula use as a positive outcome and prolonged use of a tunneled catheter as a negative outcome. With the growing recognition that some patients have exhausted options for an arteriovenous fistula, or have comorbidities that may limit the success of AVF creation, joint reporting of the measures accounts for all three vascular access options. The fistula measure adjusts for patient factors where fistula placement may be either more difficult or not appropriate and acknowledges that in certain circumstances an AV graft may be the best access option. This paired incentive structure that relies on both measures reflects consensus best practice, and supports maintenance of the gains in vascular access success achieved via the Fistula First/Catheter Last Project and ESRD Network quality improvement projects over the last decade.

United States Renal Data System. 2018 USRDS annual data report: Epidemiology of kidney disease in the United States. National Institutes of Health, National Institute of Diabetes and Digestive and Kidney Diseases, Bethesda, MD, 2018

S.4. Numerator Statement: The numerator is the number of adult patient-months in the denominator who were on maintenance hemodialysis using a catheter continuously for three months or longer as of the last hemodialysis session of the reporting month.

S.6. Denominator Statement: All patients at least 18 years old as of the first day of the reporting month who are determined to be maintenance hemodialysis patients (in-center and home HD) for the complete reporting month at the same facility.

When used for public reporting, the measure calculation will be restricted to facilities with at least 11 patients in the reporting month. This restriction is required to ensure patients cannot be identified due to small cell size.

S.8. Denominator Exclusions: Exclusions that are implicit in the denominator definition include:

• Pediatric patients (<18 years old)

• Patients on Peritoneal Dialysis

• Patient-months on in-center or home hemodialysis for less than a complete reporting month at the same facility

In addition, the following exclusions are applied to the denominator:

Patients with a catheter that have limited life expectancy:

• Patients under hospice care in the current reporting month

• Patients with metastatic cancer in the past 12 months

• Patients with end stage liver disease in the past 12 months

• Patients with coma or anoxic brain injury in the past 12 months

De.1. Measure Type: Outcome: Intermediate Clinical Outcome

S.17. Data Source: Claims, Registry Data

S.20. Level of Analysis: Facility

IF Endorsement Maintenance – Original Endorsement Date: Dec 09, 2016 **Most Recent Endorsement Date:** Dec 09, 2016

IF this measure is included in a composite, NQF Composite#/title:

IF this measure is paired/grouped, NQF#/title:

De.4. IF PAIRED/GROUPED, what is the reason this measure must be reported with other measures to appropriately interpret results? N/A

Preliminary Analysis: Maintenance of Endorsement

To maintain NQF endorsement, endorsed measures are evaluated periodically to ensure that the measures still meets the NQF endorsement criteria ("maintenance"). The emphasis for maintaining endorsement is focused on how effective the measure is for promoting improvements in quality. Endorsed measures should have some experience from the field to inform the evaluation. The emphasis for maintaining endorsement is noted for each criterion.

Criteria 1: Importance to Measure and Report

1a. Evidence

Maintenance measures – less emphasis on evidence unless there is new information or change in evidence since the prior evaluation.

1a. Evidence. The evidence requirements for a *structure, process or intermediate outcome* measure is that it is based on a systematic review (SR) and grading of the body of empirical evidence where the specific focus of the evidence matches what is being measured. For measures derived from patient report, evidence also should demonstrate that the target population values the measured process or structure and finds it meaningful.

The developer provides the following evidence for this measure:

- **Systematic Review of the evidence specific to this measure?** ☒ **Yes** ☐ **No**
- **Quality, Quantity and Consistency of evidence provided?** ☒ **Yes** ☐ **No**
- **Evidence graded?** ☒ **Yes** ☐ **No**

Summary of prior review in 2016

- In 2016, the developer provided evidence to support the measure based on 2006 National Kidney Foundation's (NKF) Kidney Disease Outcomes Quality Initiative (KDOQI) Clinical Practice Guideline for Vascular Access. The guidelines provided the order of preference for placement of fistulae in patients with kidney failure who choose hemodialysis as their initial mode of kidney replacement therapy (KRT).
- The developer's rationale provided in 2016 for this intermediate clinical outcome measure is that there is an association between type of vascular access used for hemodialysis and patient mortality; this measure focuses on the process of assessing long term catheter use at chronic dialysis facilities. The developer provides evidence suggesting that long term catheter use is correlated with the highest mortality risk and arteriovenous fistula use has the lowest risk of mortality. Arteriovenous grafts (AVG) have been found to have a risk of death that is higher than AVF but lower than catheters.
- The developer notes that this measure is intended to be jointly reported with the Hemodialysis Vascular Access- Standardized Fistula Rate. Used together, the two vascular access quality measures consider Arterial Venous (AV) fistula use as a positive outcome and prolonged use of a tunneled catheter as a negative outcome.
- The developer provides the following linkage between the measure focus and a desired health outcome:

  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.
- The developer references clinical practice guidelines (NKF: KDOQI Clinical Practice Guidelines and Clinical Practice Recommendations for 2006 Updates). The order of preference for placement of fistulae in patients with kidney failure who choose HD as their initial mode of KRT are listed in descending order. The guidelines have all been assigned a Grade B (moderately strong evidence) rating.
- The Committee agreed in 2016 that the rationale for the measure and the evidence to support it were sufficient

Changes to evidence from last review

☐ **The developer attests that there have been no changes in the evidence since the measure was last evaluated.**

☒ **The developer provided updated evidence for this measure:**

Updates:

- When this measure was originally submitted for NQF endorsement, the evidence to support the measure was based largely on the National Kidney Foundation (NKF) KDOQI Clinical Practice Guideline for Vascular Access published in 2006. The NKF recently made substantial revisions to these guidelines that were released on 3/12/20.
    - The revised guidelines emphasize a patient-focused approach that recommends the development of an End Stage Kidney Disease (ESKD) Life-Plan, and urges providers to not only consider the current vascular access, but subsequent access needs as well in the context of a comprehensive evaluation of the patient's lifetime with ESKD.

- In general, the evidence for the above guidelines has been rated as either low or moderate, with many of the guidelines relying on expert opinion.

- Developer conducted a literature review to supplement the KDOQI guidelines (literature reviewed through 2017) by using the following search in PubMed: "Arteriovenous fistula OR venous catheter AND dialysis AND published January 1, 2017 – 2020 (present)."
    - In general, the recent articles offer additional support for the general concepts laid out in the KDOQI guidelines that AV fistula continue to be the preferred vascular access for most, but not all patients on dialysis, and that long-term catheters are associated with higher rates of infection and potentially mortality as well.
    - Long-term catheters are still viewed as the least desirable vascular access, primarily due to the increased risk of blood-stream infections, with increased recognition of certain patient characteristics and scenarios where this access type may be the most appropriate.

Questions for the Committee:

- Does the Committee agree that the evidence provided by the developer is updated, directionally the same, and stronger compared to that for the previous NQF review?

Guidance from the Evidence Algorithm

Intermediate clinical outcome measure based on systematic review (Box 3) → QQC presented (Box 4) → Quantity: high; Quality: high; Consistency: high (Box 5) → Moderate (Box 5b) → High

Preliminary rating for evidence: ☒ **High** ☐ **Moderate** ☐ **Low** ☐ **Insufficient**

1b. Gap in Care/Opportunity for Improvement and 1b. Disparities

Maintenance measures – increased emphasis on gap and variation

1b. Performance Gap. The performance gap requirements include demonstrating quality problems and opportunity for improvement.

- Analysis of CROWNWeb data from January 2018 – December 2018 indicated the facility-level mean percentage of patient-months with a long-term catheter was 12.4% (SD=7.3%).
- Distribution: Min=0%, 1st quartile=7.8%, median=11.2%, 3rd quartile=15.4%, Max=89.9%.

Disparities

- Using data from January – December 2018, age, sex, race, ethnicity, dialysis vintage, employment status, Medicare coverage, and Area Deprivation Index (ADI) were evaluated in a logistic regression model for long-term catheter use.
- Age, sex, ethnicity, dialysis vintage, and employment status are statistically significant predictors for odds of long-term catheter use.
    - Females had a 44% higher odds of having a long-term catheter;
    - younger age (18-24 years) and age 25-59 were associated with higher odds of long-term catheter use (84%, and 18% respectively) compared to patients 60-75 years of age.
    - Hispanics had lower odds of having a long-term catheter (compared to non-Hispanics). Neither dual-eligible status nor area level deprivation (ADI) were statistically significantly associated with odds of long-term catheter use.
- Age:
    - For the 18-<25 age group, the Odds Ratio (95% CI) is 1.84 (1.41, 2.40), P-value is <0.001.

- For the 25-<60 age group, the Odds Ratio (95% CI) is 1.18 (1.12, 1.25), P-value is <0.001.
- The 60-<75 age group was used as the reference group.
- For the 75+ age group, the Odds Ratio (95% CI) is 1.06 (0.99, 1.13), P-value is 0.097.

- Sex:
  - For Female: the Odds Ratio (95% CI) is 1.44 (1.37, 1.51), P-value is <0.001.
  - Male was used as the reference group.
- Race:
  - White was used as the reference group.
  - For Black: the Odds Ratio (95% CI) is 1.00 (0.93, 1.07), P-value is 0.972.
  - For Other race: the Odds Ratio (95% CI) is 0.85 (0.76, 0.96), P-value is 0.008.
  - Ethnicity:
  - For Hispanic: the Odds Ratio (95% CI) is 0.80 (0.73, 0.87), P-value is <0.001.
  - Non-Hispanic was used as the reference group.
- Employment Status:
  - Employed was used as the reference group.
  - For Unemployed: The Odds Ratio (95% CI) is 1.15 (1.07, 1.25), and the P-value is <0.001.
  - For Other: The Odds Ratio (95% CI) is 1.21 (1.13, 1.30), and the P-value is <.001.
- Medicare Coverage:
  - Dual eligibility: the Odds Ratio (95% CI) is 1.04 (0.99, 1.09), and the P-value is 0.154.
  - Non-Dual eligibility was used as the reference group.
- ADI (zipcode-level): National percentile ADI score: The Odds Ratio (95% CI) is 1.00 (1.00, 1.00), and the P-value is 0.704.

Questions for the Committee:

- Developer's analysis indicates that facility-level mean percentage of patient-months with a long-term catheter was 12.4% (SD=7.3%). Is there a gap in care that warrants a national performance measure?

Preliminary rating for opportunity for improvement: ☐ **High** ☒ **Moderate** ☐ **Low** ☐ **Insufficient**

Committee Pre-evaluation Comments:
Criteria 1: Importance to Measure and Report (including 1a, 1b, 1c)

1a. Evidence to Support Measure Focus

- The evidence presented is from expert opinion and retrospective data so low grade
- No concerns
- included
- patient choice and comorbid conditions are issues
- reference to revisions to KDOQI CPG and interval lit review
- Evidence includes recent studies and KDOQI guidelines (substantial revisions to guidelines)
- Intermediate clinical outcome--there is an association between type of vascular access used for hemodialysis and patient mortality. measure long term catheter rate to assess value to identify patients who do not have an av fistula or ac graft to evaluation for an av fistula or graft by a

qualified dialysis vascular access provider to increase fistula/graft rate to lower catheter rate to lower patient mortality

- evidence OK
- Strong evidence
- I am not aware of any new studies outside of the KDOQI update cited.
- measure applies directly to type of access and risk of patient mortality
- appropriate no concerns
- Evidence appropriate and directly related to outcomes
- KDIGO guidelines updated 3/2020 evidence was rated low to moderate with guidelines related to expert opinions. Guidelines recommended patient choice be considered based on life plan.

1b. Performance Gap

- Low. There is no universally established percentage for an acceptable CVC rate
- Gaps were presented.
- moderate
- moderate
- Data shows improving performance though gap that still exists is considered important given advantages to AVF; sub-group data disparities shared
- Disparities data provided; younger age and female sex associated with higher LTC use
- Analysis of crownweb data from jan 2018 to dec 2018 patient months with long term catheter was 12.4%. Disparities - data from jan 2018 to dec 2018 age, sex, racem ethnicitym dialysis vintage, employment, medicare coverage and area deprivation index; age, sex, ethnicity, dialysis vintage and employment status predictors of oddsfor long term catheter use. females had a 44% higher odds of long term catheterl younger age 18-24 and age 25-59 higher odds of long term catheter use compared to patients 60-75 years of age; hispanicshad lower odds of having long term catheters
- continues to be a performance gap across facilities
- Gap exists
- Corwnweb data cited for performance gap. Disparities of age, sex, ethnicity, dialysis vintage and employment status discussed. Review panel rated the opportunity for improvement Moderate; I concure
- potential disparity in catheteruse was provided for race ,age ,sex
- yes
- Performance gap clearly demonstrated
- CVC rates continue to decline. Need to add exclusion criteria and risk adjustments

Criteria 2: Scientific Acceptability of Measure Properties

2a. Reliability: Specifications and Testing

2b. Validity: Testing; Exclusions; Risk-Adjustment; Meaningful Differences; Comparability; Missing Data

Reliability

2a1. Specifications requires the measure, as specified, to produce consistent (reliable) and credible (valid) results about the quality of care when implemented. For maintenance measures – no change in emphasis – specifications should be evaluated the same as with new measures.

2a2. Reliability testing demonstrates if the measure data elements are repeatable, producing the same results a high proportion of the time when assessed in the same population in the same time period and/or that the measure score is precise enough to distinguish differences in performance across providers. For maintenance measures – less emphasis if no new testing data provided.

Validity

2b2. Validity testing should demonstrate the measure data elements are correct and/or the measure score correctly reflects the quality of care provided, adequately identifying differences in quality. For maintenance measures – less emphasis if no new testing data provided.

2b2-2b6. Potential threats to validity should be assessed/addressed.

Composite measures only:

2d. Empirical analysis to support composite construction. Empirical analysis should demonstrate that the component measures add value to the composite and that the aggregation and weighting rules are consistent with the quality construct.

Complex measure evaluated by Scientific Methods Panel? ☒ **Yes** ☐ **No**

Evaluators: Scientific Methods Panel Subgroup 3

Methods Panel Review (Combined)

Methods Panel Evaluation Summary:

This measure was reviewed by the Scientific Methods Panel but was not discussed. A summary of the measure and the Panel evaluation is provided below.

Reliability

- Ratings for reliability: H-4; M-5; L-0; I-0 → Measure passes
- Reliability testing conducted at the measure score level by calculating an inter-unit reliability (IUR) with bootstrapping; IUR = 0.76, No PIUR was provided
- Some reviewers noted concerns with clarity of the specifications and accurately identifying comorbidities for the specifications, but generally reviewers agreed the specifications were acceptable.
- Reviewers found the reliability estimate (IUR) to be acceptable.

Validity

- Ratings for validity: H-1; M-6; L-2; I-0 → Measure passes
- Validity testing conducted at the measure score level by assessing the relationship between facility level quintiles of performance scores and the SMR and SHR using Poisson regression:
- SMR: the relative risk of mortality showed statistically significant increases as the performance measure quintile increased from the reference group (combined Q1 and Q2) to quintile 5.
    - Quintile 3, RR = 1.03 (95% CI: 1.01, 1.05; p = 0.004)
    - Quintile 4, RR = 1.02 (95% CI: 1.00, 1.04; p = 0.063)
    - Quintile 5, RR = 1.08 (95% CI: 1.05, 1.10; p<0.001).

- SHR: the relative risk of hospitalization increased as the performance measure quintile increased from the reference group (combined Q1 and Q2).
    - Quintile 3, RR = 1.05 (95% CI: 1.05, 1.06; p<0.001)
    - Quintile 4, RR = 1.07 (95% CI: 1.06, 1.08; p<0.001)
    - Quintile 5, RR = 1.10 (95% CI: 1.09, 1.10; p<0.001).
- Reviewers expressed some concerns with the approach to demonstrate validity and found the results modest, but generally acceptable.
- This measure is not risk adjusted. Some reviewers questioned the rationale for not risk adjusting but most reviewers generally found the rationale acceptable.

Questions for the Committee regarding reliability:

- Do you have any concerns that the measure can be consistently implemented (i.e., are measure specifications adequate)?
- The Scientific Methods Panel is satisfied with the reliability testing for the measure. Does the Committee think there is a need to discuss and/or vote on reliability?

Questions for the Committee regarding validity:

- Do you have any concerns regarding the validity of the measure (e.g., exclusions, risk-adjustment approach, etc.)?
- The Scientific Methods Panel is satisfied with the validity analyses for the measure. Does the Committee think there is a need to discuss and/or vote on validity?

Preliminary rating for reliability: ☐ **High** ☒ **Moderate** ☐ **Low** ☐ **Insufficient**

Preliminary rating for validity: ☐ **High** ☒ **Moderate** ☐ **Low** ☐ **Insufficient**

Committee Pre-evaluation Comments:
Criteria 2: Scientific Acceptability of Measure Properties (including all 2a, 2b, and 2c)

2a1. Reliability-Specifications

- moderate - agree with methods committee.
- No concerns
- moderate
- moderate
- appears satisfactory
- Data elements clearly defined
- that the measure produces consistent, reliable, and credible, valid, results about quality of care when implemented.
- reliability specifications ok
- Reliable
- none that were not stated by the reviewers
- data elements are defined
- yes
- No concerns
- No concerns - IUR similar to previous results

2a2. Reliability – Testing

- moderate - agree with methods committee.
- Reporting mechanisms through CROWNWeb have at times bee said to be delayed, and will certainly be impacted by the pandemic.
- moderate
- comorbid inclusions too limited
- IUR of 0.76 suggests most variation between centers based on true differences in performance
- Overall IUR 0.76, not stratified by size of dialysis facility
- Concerns with clarity of the specifications and accurately identifying comorbities for the specifications
- no concerns
- no
- no
- none
- no concerns
- My concerns are the same as those I listed for 2977. This metric now has exclusions for patients with limited life expectancy. However, it does not go far enough - - other patient factors determine the likelihood of conversion from CVC to AVF, including age, sex, comorbidities including diabetes, peripheral vascular disease and others. Most importantly - - this revised metric now includes new guidance from KDOQI for a patient-focused approach, a comprehensive evaluation of the patient's lifetime with ESKD. Some patients choose to construct their lifetime plan with no further attempts at AVF construction. A patient's informed choice MUST be included in this mertric, an exclusion as important as is limited life expectancy.
- No concerns

2b1. Validity -Testing

- moderate - agree with methods committee.
- No concerns
- comorbid conditions need expansion(frailty)
- as above
- regression models to measure association between quintiles of facility performance with this measure vs SMR and SHR; modest associations that with increased duration of Cath use there are higher SMRs and SHRs
- Association between LTC and SHR and SMR examined
- No concerns
- no concerns
- valid measure
- no
- none
- no
- No concerns
- Associated with SMR and SHR

2b4-7. Threats to Validity

No concerns

- Data may be delayed by pandemic but should eventually get reported.

- see above
- not clear if data adjusted for impact of gender and fistual outcomes
- no apparent significant threats to validity
- 21.4% patient months unable to determine presence of comorbidities for exclusions related to limited life expectancy
- Testing sample was adequate thus demonstrated sufficient validity for conclusions of care
- Although less a concern with this measure than AVF measure since it is >3 months use, the current mechanism of facility attribution could lead to a few potential problems: 1) penalizing facilities with a predominance of incident patients 2) discouraging facilities from accepting patients with catheters from other facilities
- No significant threats to validity
- 7 out of 9 reviewers had no conerns.
- no
- no concerns
- See my comments above under 7.2a2.
- Missing vascular access data is counter as a catheter is problematic.Validity is weakened due to not enough exclusion criteria and no case mix adjustment.

2b2-3. Other Threats to Validity

- moderate - agree with methods committee.
- Pandemic impact on access surgery is likely to influence inter unit comparisons
- comorbid conditions need expansion
- as above
- argument against risk adjustment seems a bit arcane
- No risk-adjustment (measure has patient-level exclusion criteria)
- Results support validity
- 1.The criteria for hospice determination on p 47 is not clear. Also, if a patient is enrolled in a hospice program, can you confirm that claims for hospice are submitted each month? 2.I like the exclusion for patients with limited life expectancy (i.e., hospice). What about also excluding those who are not candidates for an AVF (e.g., exhausted vascular access, insufficient vascular anatomy)? What was the reason why the TEP could not reach consensus on this matter? 3.The matter regarding missing data for exclusion conditions is not completely clear. While LTC performance results w/ and w/o exclusions that can be identified are highly correlated, does this necessarily dismiss potential bias due to missing data for end of life comorbidities and failure to exclude potentially additional unidentified patients for exclusion 4. Could the developer summarize why the AVF measures was adjusted for comorbidities to achieve a standardized value while the catheter measure was not? Do they believe the latter is unnecessary because these measures should be interpreted together?
- no sig threats to validity
- Measure not risk adjusted; panel had concerns
- n/a
- appropriate
- N/A
- Need to extend time for CVC to AV conversions especially as more transpositions of ACF's are occurring with increased wait times for use. Need to consider access failure as an exclusion.

Criterion 3. Feasibility

Maintenance measures – no change in emphasis – implementation issues may be more prominent

3. Feasibility is the extent to which the specifications including measure logic, require data that are readily available or could be captured without undue burden and can be implemented for performance measurement.

- Developer notes that the data sources for the measure are routinely generated during the provision of care.
- Developer notes that data elements are in defined fields in a combination of electronic sources.
    - Data collection is accomplished via Medicare Claims and CROWNWeb, a web-based and electronic batch submission platform maintained and operated by CMS contractors.
    - Measures reported on DFC are reviewed on a regular basis by dialysis facility providers.
    - Review of comments and questions received in the past for the long term catheter rate showed very few instances of concern expressed about inaccurate or missing data

Questions for the Committee:

- Are the required data elements routinely generated and used during care delivery?
- Are the required data elements available in electronic form, e.g., EHR or other electronic sources?

Preliminary rating for feasibility: ☒ **High** ☐ **Moderate** ☐ **Low** ☐ **Insufficient**

Committee Pre-evaluation Comments:
Criteria 3: Feasibility

3. Feasibility

- No concerns
- No concerns
- none
- no issues
- appears highly feasible
- As specified, data collection feasible
- data souces are all measures that are routinely generated during the provision of care and data elements are in defined fields in a combination of electronic sources. No concerns
- no concerns
- no significant concerns about feasibility
- Data collection via Medicare Claims and CROWNWeb.
- elements are routinely collected
- none
- None
- Data is routinely measured and available electronically - no concerns

Criterion 4: Usability and Use

Maintenance measures – increased emphasis – much greater focus on measure use and usefulness, including both impact/improvement and unintended consequences

4a. Use (4a1. Accountability and Transparency; 4a2. Feedback on measure)

4a. Use evaluate the extent to which audiences (e.g., consumers, purchasers, providers, policymakers) use or could use performance results for both accountability and performance improvement activities.

4a.1. Accountability and Transparency. Performance results are used in at least one accountability application within three years after initial endorsement and are publicly reported within six years after initial endorsement (or the data on performance results are available). If not in use at the time of initial endorsement, then a credible plan for implementation within the specified timeframes is provided.

Current uses of the measure

Publicly reported? ☒ **Yes** ☐ **No**

Current use in an accountability program? ☒ **Yes** ☐ **No** ☐ **UNCLEAR**

OR

Planned use in an accountability program? ☐ **Yes** ☐ **No**

Accountability program details

- Results of this measure are currently reported on Dialysis Facility Compare, and are slated for reporting in the ESRD Quality Incentive Program for PY 2021.
    - Public Reporting: Dialysis Facility Compare
    - Payment Program: ESRD QIP
- All Medicare-certified dialysis facilities are eligible for reporting in both programs (approximately 7,000 dialysis facilities).
- The measure developer (UM-KECC) produces and distributes the DFC data under contract with CMS. Other CMS contractors calculate and distribute the ESRD QIP measure results.

4a.2. Feedback on the measure by those being measured or others. Three criteria demonstrate feedback: 1) those being measured have been given performance results or data, as well as assistance with interpreting the measure results and data; 2) those being measured and other users have been given an opportunity to provide feedback on the measure performance or implementation; 3) this feedback has been considered when changes are incorporated into the measure

Feedback on the measure by those being measured or others

- Results of this measure are currently reported on Dialysis Facility Compare, and are slated for reporting in the ESRD Quality Incentive Program for PY 2021. Each program has a helpdesk and supporting documentation available to assist with interpretation of the measure results
- For both programs, feedback can be provided any time through contacting the dialysisdata.org and QIP helpdesk respectively
- The developer notes that the comments received during DFC preview periods tend to be technical in nature, asking for clarification on how the LTC is calculated for particular facilities, including questions about patient assignment and requests for confirmation of patient vascular access type in a specific month. UM-KECC investigates all inquiries received about specific patients and works with facilities to ensure that they understand their measure results and that data discrepancies are resolved.
- For ESRD QIP, the developer states that since the LTC was first proposed in the PY 2021 proposed rule, several commenters requested that this measure account for situations for which the patient has

elected not to have a fistula (patient choice/preference). CMS also received comments about facilities possibly being doubly penalized if they have low fistula rates, and high catheter rates, and also do not get credit for grafts. Comments were also received on additional clinical risk adjustors and exclusions, including exhausting all other vascular access options.

Additional Feedback: None

Questions for the Committee:

- How have (or can) the performance results be used to further the goal of high-quality, efficient healthcare?
- Has the measure been appropriately vetted in real-world settings by those being measured or others?

Preliminary rating for Use: ☒ **Pass** ☐ **No Pass**

4b. Usability (4a1. Improvement; 4a2. Benefits of measure)

4b. Usability evaluate the extent to which audiences (e.g., consumers, purchasers, providers, policymakers) use or could use performance results for both accountability and performance improvement activities.

4b.1 Improvement. Progress toward achieving the goal of high-quality, efficient healthcare for individuals or populations is demonstrated.

Improvement results [Impact/trends over time/improvement]

4b2. Benefits vs. harms. Benefits of the performance measure in facilitating progress toward achieving high-quality, efficient healthcare for individuals or populations outweigh evidence of unintended negative consequences to individuals or populations (if such evidence exists).

Unexpected findings (positive or negative) during implementation

Potential harms

- The developer did not note any unintended consequences or unexpected findings during implementation of this measure.

Additional Feedback: None

Questions for the Committee:

- How can the performance results be used to further the goal of high-quality, efficient healthcare?
- Do the benefits of the measure outweigh any potential unintended consequences?

Preliminary rating for Usability and use: ☐ **High** ☒ **Moderate** ☐ **Low** ☐ **Insufficient**

Committee Pre-evaluation Comments:
Criteria 4: Usability and Use

4a1. Use - Accountability and Transparency

- Standardized ratios are more difficult to interpret than risk adjusted rates
- Patient choice has been emphasized but not incorporated
- feedback available
- feedback avenues available
- measure being used with opportunity for feedback

- Publicly reported on DFC and used in the ESRD QIP
- Results of measure are currently reported on dialysis facility compare .feedback can be provided any time through contacting the dialysisdata.org and QIP helpdesk. feedback has been considered when changes are incorported into the measure
- yes, well described
- usable and transparent
- Use - reported via Dialysis Facility Compare and ESKD QIP
- measures are currently reported
- yes appropriate
- Vascular access is being reported and feedback to facilities and clinicians does drive QI efforts
- No concerns

4b1. Usability – Improvement

- Standardized ratios are more difficult to interpret than risk adjusted rates
- Patients may have less choice of facilities and/or AV access procedures that are undesirable.
- addition of frailty index may be useful, and prevent repetitive invasive procedures being done with hope of obtaining an alternative vascular access
- repetitive attempts at fistula placement versus graft placement is a potential unintended and harmful outcome
- in use with DFC and part of PY2021 QIP
- Reducing long-term catheter use remains an important focus of quality improvement
- Progresss toward achieving the goal of high quality efficient healthcare for ubdividuals and populations studied. developer did not note any unintended consequences or unexpected findings during implementation of measure
- yes, benefits outweigh harms
- benefits>>>harm
- Improvement - impact/trends over time/improvement. Benefits of the measure is identified as providing data that will result in achieving high-quality, efficient health care. No unintended consequences or unexpected findings identified by developer.
- no unintended consequences noted
- appropriate
- Usability is limited by the concerns I have listed to validity
- Harm to include excessive surgeries to produce AVF. Patient choice not included in the exclusion criteria

Criterion 5: Related and Competing Measures

Related or competing measures

The developer identified the following measure as related:

- 2594 : Optimal End Stage Renal Disease (ESRD) Starts

NQF staff identified additional related measures that the Committee reviewed during the original endorsement in 2016. The Committee was unable to discuss related and competing measures during the in-

person meeting and had the opportunity to do so during the post-comment call. The Committee determined at that time that these measures were related but did not need to be further harmonized:

- 0251: Vascular Access—Functional Arteriovenous Fistula (AVF) or AV Graft or Evaluation for Placement
- 0256: Hemodialysis Vascular Access-Minimizing use of catheters as Chronic Dialysis Access
- 0257: Hemodialysis Vascular Access-Maximizing Placement of Arterial Venous Fistula (AVF)
- 2978: Hemodialysis Vascular Access: Long-term Catheter Rate

Harmonization

- The developer states that the measure specifications are not completely harmonized, but provides a rationale stating:
    - The setting focus of NQF #2594 addresses a different provider type which falls outside the purview of measures evaluating dialysis facility performance on fistula use. The developer highlights a fundamental difference in the measure target populations, setting and intent that cannot be harmonized. Additionally, the measure is limited to incident patients, while the SFR includes both incident and prevalent patients as the measured population.

Committee Pre-evaluation Comments: Criterion 5: Related and Competing Measures

5. Related and Competing

- competing meaure is the standardized fistula rate
- Yes. No concerns
- in some cases a graft would be preferable to the repetitive surgeries and procedures needed to create a fistula. in this regard the standardized fistula rate measure may inadvertently be leading to a higher rate of procedures and perhaps a higher incidence of catheter use
- requirement for successful of fistula competes with placement of a graft and may inadvertently result in longer term catheter use
- 0251 vascula access - functional art fistula or av graft; 0256 hemodialysis vascular access-minimizing use of catheters as chronic dialysis access; 0257hemodialysis vascular access -maximizing placement of AVF; 2978 hemodialysis vascular access -ele long-term catheter rate. measure specifications are not completlyharmonized. Setting focus of 2594 falls outside purview of measure evaluating dialysis facility performance on fistula use. Fundamental difference in measure target populations,setting and intent that cannot be harmonized
- compatible
- Developers identifed 2594 as related; NQF staff identified 0251,0256,0257 and 2978 as related but not needing further harmonized.
- there are other completing measures but they do not need to be harmonized
- no overlapp
- Yes, all vascular access measures should be re-assessed and harmonized in light of new exclusion criteria
- No concerns

Public and Member Comments

Comments and Member Support/Non-Support Submitted as of: Month/Day/Year

- **Of the XXX NQF members who have submitted a support/non-support choice:**
  - XX support the measure
  - YY do not support the measure

Combined Methods Panel Scientific Acceptability Evaluation

Scientific Acceptability: Preliminary Analysis Form

Measure Number: 2978

Measure Title: Hemodialysis Vascular Access: Long-term Catheter Rate

Type of measure:

☒ **Process** ☐ **Process: Appropriate Use** ☐ **Structure** ☐ **Efficiency** ☐ **Cost/Resource Use**

☒ **Outcome** ☐ **Outcome: PRO-PM** ☒ **Outcome: Intermediate Clinical Outcome** ☐ **Composite**

Panel Member #7 Despite sponsor's designations an intermediate outcome, this appears clearly to be a process measure.

Panel Member #8 Although this measure is classified as an intermediate outcome, this measure appears to be a process measure.

Data **Source:**

☒ **Claims** ☐ **Electronic Health Data** ☐ **Electronic Health Records** ☐ **Management Data**
☐ **Assessment Data** ☐ **Paper Medical Records** ☐ **Instrument-Based Data** ☒ **Registry Data**
☐ **Enrollment Data** ☐ **Other**

Level of Analysis:

☐ **Clinician: Group/Practice** ☐ **Clinician: Individual** ☒ **Facility** ☐ **Health Plan**
☐ **Population: Community, County or City** ☐ **Population: Regional and State**
☐ **Integrated Delivery System** ☐ **Other**

Measure is:

☒ **New** ☐ **Previously endorsed (**NOTE: Empirical validity testing is expected at time of maintenance review; if not possible, justification is required.)

RELIABILITY: SPECIFICATIONS

1. **Are submitted specifications precise, unambiguous, and complete so that they can be consistently implemented?** ☐ **Yes** ☐ **No**

   Submission document: "MIF_xxxx" document, items S.1-S.22

   NOTE*: NQF staff will conduct a separate, more technical, check of eCQM specifications, value sets, logic, and feasibility, so no need to consider these in your evaluation.*

2. **Briefly summarize any concerns about the measure specifications.**

   Panel Member #1 none

Panel Member #3 I have only one concern. Comorbidty is defined by dual instruments, including the presence of comorbid conditions on form CMS-2728, which is completed at dialysis initiation, and the presence of diagnosis code in Medicare claims. Claims are not available in patients without Medicare Parts A, B, or C, and even in those patients with Medicare Part C, only inpatient claims are available. The steward compensates for this information error by including a binary indicator regarding Medicare Parts A, B, or C enrollment. However, it is not clear to me that this approach is necessarily superior to drawing comorbidity data only from form CMS-2728. Unfortunately, fitted parameters in the risk adjustment model are not displayed.

Panel Member #4 No concerns

Panel Member #6 May want to define "maintenance hemodialysis patients."

Panel Member #7 There are two exclusions that would seem appropriate that are not mentioned:

1) Patients who within the first six months of ESRD dialysis and may be in process of being referred for fistula creation—or who may have fistula which they are waiting to mature (which may take up to 4 months)
2) Patients who have previously had fistula or fistulae and/or shunts and they have failed and they are awaiting another attempt or they are out of options

Panel Member #8 None.

RELIABILITY: TESTING

Submission document: "MIF_xxxx" document for specifications, testing attachment questions 1.1-1.4 and section 2a2

3. **Reliability testing level** ☒ **Measure score** ☐ **Data element** ☐ **Neither**
4. **Reliability testing was conducted with the data source and level of analysis indicated for this measure**
   ☒ **Yes** ☐ **No**
5. If score-level and/or data element reliability testing was NOT conducted or if the methods used were NOT appropriate, was **empirical <u>VALIDITY</u> testing** of <u>patient-level data</u> conducted?

   ☐ **Yes** ☒ **No**
6. **Assess the method(s) used for reliability testing**

   Submission document: Testing attachment, section 2a2.2

   Panel Member #1 No concerns

   Panel Member #2 The methods used were appropriate – this is one of a large set of measures from CMS set in the context of dialysis care, and the measure developer regularly uses the signal-to-noise ratio method suggested by Adams to assess reliability.

   Panel Member #3 IUR was estimated.

   Panel Member #4 Same methods from previous testing applied

   Panel Member #6 Used Inter-Unit Reliability method, which is appropriate.

   Panel Member #7 Appropriate; within vs inter-center variability using appropriate methodology

   Panel Member #8 Method is appropriate – compare within vs. between facility variation (signal to noise).

   Panel Member #9 The developers report inter unit reliability (IUR) which is the conventional proportion of signal variation definition of reliability.
7. **Assess the results of reliability testing**

   Submission document: Testing attachment, section 2a2.3

Panel Member #1 The IUR is 0.76, which indicates that 76% of the variation in the annual long-term catheter rate can be attributed to between-facility differences in performance (signal) and 24% to the within-facility variation (noise).

Panel Member #2 The methods used were appropriate – this is one of a large set of measures from CMS set in the context of dialysis care, and the measure developer regularly uses the signal-to-noise ratio method suggested by Adams to assess reliability.

Panel Member #3 The estimated IUR is equal to 0.76 in 2018.

Panel Member #4 Results were similar to previous testing

Panel Member #6 IUR=0.76 which means 76% of the variation can be attributed to signal and 24% can be attributed to noise. Acceptable.

Panel Member #7 76% of variance likely due to inter-center differences

Panel Member #8 Results indicate a reasonable amount of performance due to quality signal (76%).

Panel Member #9 The estimated IUR (proportion of signal variation) was 0.76. This is modest but good in comparison to many other quality measures, especially outcomes.

8. Was the method described and appropriate for assessing the proportion of variability due to real differences among measured entities? NOTE: If multiple methods used, at least one must be appropriate.

   Submission document: Testing attachment, section 2a2.2

   ☒ **Yes**

   ☐ **No**

   ☐ **Not applicable** (score-level testing was not performed)

9. Was the method described and appropriate for assessing the reliability of ALL critical data elements?

   Submission document: Testing attachment, section 2a2.2

   ☒ **Yes**

   ☐ **No**

   ☒ **Not applicable** (data element testing was not performed)

10. **OVERALL RATING OF RELIABILITY** (taking into account precision of specifications and all testing results):

    ☒ **High** (NOTE: Can be HIGH only if score-level testing has been conducted)

    ☒ **Moderate** (NOTE: Moderate is the highest eligible rating if score-level testing has not been conducted)

    ☐ **Low** (NOTE: Should rate LOW if you believe specifications are NOT precise, unambiguous, and complete or if testing methods/results are not adequate)

    ☐ **Insufficient** (NOTE: Should rate INSUFFICIENT if you believe you do not have the information you need to make a rating decision)

11. **Briefly explain rationale for the rating of OVERALL RATING OF RELIABILITY and any concerns you may have with the approach to demonstrating reliability.**

    Panel Member #1 The methods and on the reliability analyses were adequate. I would have liked to see additional analyses which stratified by site volume.

    Panel Member #2 The measure score reliability is in the range of .75, and the developer identifies this as "high" using Landis and Koch labels for kappa agreement that are probably not appropriate or generalizable to the setting of reliability of health care performance measures. Others who have empirically related reliability to probability of misclassification in provider profiling contexts have typically shown reasonably low probabilities of misclassification only with relabilities over .7 or even over .9 in some contexts. From this perspective, .75 is acceptable, but "moderate".

Panel Member #3 The IUR statistic is relatively high.

Panel Member #4 No concerns, methodology from previous testing used with similar results.

Panel Member #5 The IUR is 0.76, which indicates that 76% of the variation in the annual long-term catheter rate can be attributed to between-facility differences in performance (signal) and 24% to the within-facility variation (noise).

The result of IUR testing suggests a high degree of reliability.

Panel Member #6 No concerns.

Panel Member #7 Reliability was good for measure as it is constituted—my concerns regarding exclusions relate more to validity.

As with all of the CMS ESRD metrics which rely on the linking of multiple databases, some reassurance of the success of the linkage would be reassuring.

Panel Member #8 Reliability estimate using STN approach was acceptable.

VALIDITY: ASSESSMENT OF THREATS TO VALIDITY

12. **Please describe any concerns you have with measure exclusions.**

Panel Member #1 None

Panel Member #2 None.

Panel Member #3 I have no specific concerns. I appreciate the inclusion of all hemodialysis patients, including those without Medicare coverage and those who dialyze in the home setting. I also support the exclusion of patients with limited life expectancy, as the evolving consensus in the nephrology community is that fistula placement may be neither patient-centered nor cost-effective in this subset of the dialysis patient population.

Panel Member #4 No concerns

Panel Member #6 No concerns.

Panel Member #7 1) Failure to exclude patients in the first 6 month of dialysis for ESRD –who may be in the process of getting a fistula and/or waiting for it to mature--will bias the metric against centers with a high proportion of new dialysis patients. 2)Failure to exclude patients who have failed prior efforts at fistula or even shunt creation would bias centers taking care of difficult patients who have had appropriate referral for fistula but for one of many reasons had fistula/shunt failure

Panel Member #8 None.

Panel Member #9 None

13. **Please describe any concerns you have regarding the ability to identify meaningful differences in performance.**

Submission document: Testing attachment, section 2b4.

Panel Member #1 The distribution within the 3 catagories appear to suggest than meaningful differences exist. But it would be helpful to report the national average and the distribution of actual performance.

Panel Member #2 As noted above, the measure can only reliably identify extreme high or low outliers. It cannot identify meaningful differences in performance within the large main body of the distribution of scores.

Panel Member #3 I have no specific concerns.

Panel Member #5 For the annual percentage of patients with a long-term catheter as the performance measure, 6,095 (89.1%) facilities have achieved either as expected or better than expected performance, and 743 (10.9%) facilities have performed worse than expected (higher catheter rate).

In general, lower rates of long-term catheter use for three months or more represent better quality of care. This analysis demonstrates both practical and statistically significant differences in performance across facilities based on their proportion of patient months with a catheter for three months or greater.

It would be helpful to estimate the impact of the 10.9% since the vast majority of hospitals are not performing worse than expected.

Panel Member #7 Meaningful is the operative word—my concerns regarding validity address this issue—that said, within the definitions of the metric, it appears to be able to make a distinction among sites

Panel Member #9 None.

14. **Please describe any concerns you have regarding comparability of results if multiple data sources or methods are specified.**

Submission document: Testing attachment, section 2b5.

Panel Member #2 N/A
Panel Member #3 This item is not applicable.
Panel Member #6 N/A
Panel Member #7 As noted for all of the CMS ESRD metrics which rely on ability to merge data from multiple data sources, some documentation/confirmation of the success of the merger would be reassuring.
Panel Member #9 None

15. **Please describe any concerns you have regarding missing data.**

Submission document: Testing attachment, section 2b6.

Panel Member #1 None

Panel Member #2 No significant concerns

Panel Member #3 The inability to identify conditions supporting limited life expectancy in greater than 20% of patient-months is concerning. However, patient-months that satisfy this criterion are very likely accompanied by commercial insurance, which is correlated with younger age. Thus, the actual prevalence of limited life expectancy in this group of patient-months is likely very low.

Panel Member #4 No concerns

Panel Member #6 Missing data is counted as a "catheter".

Panel Member #7 Absence of comorbidity data (on 21.4% of patients) is concerning. Sponsors may feel that since they do not risk adjust that this is not a major concern, but I find the absence of risk adjustment problematic.

Panel Member #8 High level of missing comorbidity data (21.4% of patients)

Panel Member #9 None

16. **Risk Adjustment**

16a. **Risk-adjustment method** ☒ **None** ☒ **Statistical model** ☐ **Stratification**

16b. **If not risk-adjusted, is this supported by either a conceptual rationale or empirical analyses?**

☒ Yes ☒No ☒ Not applicable

Panel Member #7 Rationale was weak and not convincing—there may be compelling biologically and patient-centric reasons why patient is receiving hemodialysis with an indwelling catheter which do not represent lapses in care on the part of the center

Panel Member #8 (adequacy of rationale should be evaluated by standing committee)
Panel Member #9 The developers state that adjustment for age, sex, and race would mask disparities. This is a common belief but it is not true when scrutinized from a statistical perspective.

16c. **Social risk adjustment:**

16c.1 Are social risk factors included in risk model? ☒ Yes ☒ No ☒ Not applicable

16c.2 Conceptual rationale for social risk factors included? ☒ Yes ☒ No

16c.3 Is there a conceptual relationship between potential social risk factor variables and the measure focus? ☒ Yes ☒ No

Panel Member #7 Sponsors contention that none of the social risk factors—i.e. sex—have biological relationship to the metric is potentially and likely false.

16d.**Risk adjustment summary:**

Panel Member #4 2015 TEP recommended not using risk adjustment

Panel Member #7 N/**A**

16d.1 All of the risk-adjustment variables present at the start of care? ☒ Yes ☐ No

16d.2 If factors not present at the start of care, do you agree with the rationale provided for inclusion? ☐ Yes ☐ No

16d.3 Is the risk adjustment approach appropriately developed and assessed? ☒ Yes ☐ No

16d.4 Do analyses indicate acceptable results (e.g., acceptable discrimination and calibration) ☒ Yes ☐ No

16d.5.Appropriate risk-adjustment strategy included in the measure? ☒ Yes ☒ No

16e**. Assess the risk-adjustment approach**

Panel Member #1 The rationale for not risk adjusting this measure is that there isn't a subset of patient for which catherers are indicated, except those that are excluded. The underlying assumption is that quality differences based on SES shouldn't be adjusted away. This perhaps makes sense in a QI framework (directing resources to low performers) but not in a accountability framework (financially penalizing sites will low performance). This highlights the fact that validity is not uniform across measure applications.

Panel Member #2 The measure developer has chosen to do no risk adjustment**.** The rationale for this is the idea that the purpose of the measure is to disincentivize use of long-term catheterization, for all patients, in all facilities. While this makes logical sense, it should be noted that NQF endorsement is about the technical and scientific properties of measures as quality measures. The issues of use of measures as either incentives or disincentives should not be part of the NQF endorsement process – this is a user decision. If there is a logic and science basis for risk adjustment while focusing on the technical properties of the measure as a quality of care meaure, then that risk adjustment should be done in order to gain NQF endorsement.

Panel Member #3 The risk adjustment approach is reasonable. I do not fully understand why several factors that could be parameterized continuously, including age and ESRD duration, are instead parameterized categorically.

Panel Member #5 Where is th discussion for 1b**.**4?

Panel Member #6 No risk adjustment**.** Did not address the concerns from the previous evaluation e.g., length of time on dialysis and insurance coverage into consideration. These factors may contribute to facility differences.

Panel Member #7 Absence of risk adjustment is problematic

<u>For cost/resource use measures ONLY</u>:

17. **Are the specifications in alignment with the stated measure intent?**

☐ Yes ☐ Somewhat ☐ No (If "Somewhat" or "No", please explain)

18. **Describe any concerns of threats to validity related to attribution, the costing approach, carve outs, or truncation (approach to outliers):**

VALIDITY: TESTING

19. **Validity testing level: ☒ Measure score ☐ Data element ☐ Both**

20. **Method of establishing validity of the measure score:**

    ☒ **Face validity**

    ☒ **Empirical validity testing of the measure score**

    ☐ **N/A (score-level testing not conducted)**

21. **Assess the method(s) for establishing validity**

    Submission document: Testing attachment, section 2b2.

    Panel Member #1 – I am unclear why poisson

    Panel Member #4 Face validity from 2015 TEP carried forward. Poissen regression wasmodel from previous testing used when the outcomes (e.g., Standardized Mortality Ratio) were not counts and probably don't meet the assumption that the mean = variance? I am also unclear why Q1 and Q2 were combined.

    Panel Member #6 Use Poisson regression models. Appropriate method.

    Panel Member #7 Correlation with other measures and face validity of expert panel

    Panel Member #9 Validity was assessed by comparing estimates to other related metrics including the Standardized Mortality Ratio (SMR) and Standardized Hospitalization Ratio (SHR). Outcomes for mortality and hospitalization were compared across quintiles of performance on the catheter rate measure.

    Face validity was ensured through engagement of a technical expert panel (TEP) in 2015.

22. **Assess the results(s) for establishing validity**

    Submission document: Testing attachment, section 2b2.3

    Panel Member #1 Although the results generally support the hypotheses, It looks like Q3 had a lower SMR to Q4? Also, these ecological analyses do not test if patients with long term catheters have higher risk of death or hospitalization.

    Panel Member #2 The face validity results are acceptable; the empirical validity testing results are generally quite weak, but in the predicted directions for the most part.

    Panel Member #3 The lowest quintile of the measure was associated with modestly higher standardized mortality and hospitalization ratios. The associations are not clinically impressive.

    Panel Member #4 Adequate validity demonstrated and similar to previous testing

    Panel Member #6 Acceptable results.

    Panel Member #7 Correlated with mortality and hospitalization measures

    Panel Member #8 Measure was appropriately correlated with mortality and hospitalization measures

    Panel Member #9 Patients receiving care from facilites in the 3rd, 4th, and 5th quintiles of performance for the measure had higher risk of death or hospitalization compared to patients receiving care from facilities in the 1st or2nd performance quintiles. Risk ratios for quintile 5 versus 1 and 2 were 1.09 for mortality and 1.16 for hospitalization.

23. **Was the method described and appropriate for assessing conceptually and theoretically sound hypothesized relationships?**

    Submission document: Testing attachment, section 2b1.

    ☒ **Yes**

    ☐ **No**

    ☐ **Not applicable** (score-level testing was not performed)

24. **Was the method described and appropriate for assessing the accuracy of ALL critical data elements?**

    NOTE that data element validation from the literature is acceptable.

Submission document: *Testing attachment, section 2b1.*

☒ **Yes**

☐ **No**

☒ **Not applicable** (data element testing was not performed)

25. **OVERALL RATING OF VALIDITY taking into account the results and scope of all testing and analysis of potential threats.**

☒ **High** (NOTE: Can be HIGH only if score-level testing has been conducted)

☒ **Moderate** (NOTE: Moderate is the highest eligible rating if score-level testing has NOT been conducted)

☒ **Low** (NOTE: Should rate LOW if you believe that there are threats to validity and/or relevant threats to validity were not assessed OR if testing methods/results are not adequate)

☐ **Insufficient** (NOTE: For instrument-based measures and some composite measures, testing at both the score level and the data element level is required; if not conducted, should rate as INSUFFICIENT.)

26. **Briefly explain rationale for rating of OVERALL RATING OF VALIDITY and any concerns you may have with the developers' approach to demonstrating validity.**

Panel Member #1 Although I have some questions about the methods (see above) and the results are modest, they basically support the hypothesized ecological relationships. They do not address the implied patient-level hypotheses (e.g., "Long-term catheter use is also associated with higher risk of infection which may increase the risk of a life threatening infection or other poor outcomes that place patients at higher risk of mortality.")

Panel Member #2 As in the case of reliability, only score-level validity testing was done, so the moderate rating for score-level validity is the same as the moderate rating for overall validity.

Panel Member #3 The measure is a very reasonable process outcome measure. The weak associations of low measure values with standardized mortality and hospitalization ratios are unsurprising to me, as fistulas (versus catheters) are not necessarily superior. In other countries, including Canada, catheters are commonly used and infection control practices are such that outcomes associated with catheters are non-inferior. In the US, infection control in catheter-dependent dialysis patients has proven to be a challenge. For that reason, the standardized fistula rate implicitly acts as a quality guardrail.

Panel Member #4 No concerns

Panel Member #5 Results from the Poisson model indicated that the percent of patient-months with a long-term catheter was significantly associated with the risks of mortality and hospitalization.

For the 2018 SMR, the relative risk of mortality showed statistically significant increases as the performance measure quintile increased from the reference group (combined Q1 and Q2) to quintile 5. For quintile 3, RR=1.03 (95% CI: 1.01, 1.05; p=0.004), quintile 4, RR=1.02 (95% CI: 1.00, 1.04; p=0.063), and quintile 5, RR=1.08 (95% CI: 1.05, 1.10; p<0.001).

Similarly for the 2018 SHR, the relative risk of hospitalization increased as the performance measure quintile increased from the reference group (combined Q1 and Q2). For quintile 3, RR=1.05 (95% CI: 1.05, 1.06; p<0.001), quintile 4, RR=1.07 (95% CI: 1.06, 1.08; p<0.001), and quintile 5, RR=1.10 (95% CI: 1.09, 1.10; p<0.001).

The face validity form the 2015 TEP described in the previous submission also carries forward for this submission.

Panel Member #7 Absence of appropriate exclusions, absence of risk adjustment and failure to account for biological impact of sex greatly weaken validity of this measure as a metric of quality of care offered by the dialysis center.

Panel Member #8 Associations with mortality and hospitalization were modest but in the expected direction.

Panel Member #9 I gave a low rating due to the absence of a case mix adjustment and no compelling explanation for the decision not to adjust for case mix. Data presented in the measure information form indicate that cath rates are associated with age, sex, and race.

FOR COMPOSITE MEASURES ONLY: Empirical analyses to support composite construction

27. **What is the level of certainty or confidence that the empirical analysis demonstrates that the component measures add value to the composite and that the aggregation and weighting rules are consistent with the quality construct?**

    ☐ **High**

    ☐ **Moderate**

    ☐ **Low**

    ☐ **Insufficient**

28. **Briefly explain rationale for rating of EMPIRICAL ANALYSES TO SUPPORT COMPOSITE CONSTRUCTION**

ADDITIONAL RECOMMENDATIONS

29. **If you have listed any concerns in this form, do you believe these concerns warrant further discussion by the multi-stakeholder Standing Committee? If so, please list those concerns below.**

Panel Member #2 The measure has been shown to be reliable for the purpose of identifying extreme outliers (e.g., top or bottom 10% of the score distribution). NQF endorsement should reflect that limitation. The measure should not be used for other purposes based on an "NQF-endorsed" status.

The absence of risk adjustment is somehat troubling. The stated reason, as noted above, is that the measure is intended for use as a disincentive to use of long-term catheters in dialysis. Use of a measure as an incentive or disincentive should not be part of the NQF endorsement process. The measure should be developed and submitted and endorsed as a measure of quality, period. Its use as an incentive or disincentive is a later issue to be decided by users of the measure. The measure developer could conceivably argue that the use of catheters is poor quality, no matter what the circumstances. The developer does present an argument for dealing with legitimate exceptions through exclusions rather than risk adjustment, and this argument is acceptable. However, the focus of NQF review and endorsement should be on the scientific properties of proposed measures as measures of quality, not on their future use as incentives or disincentives. It's a narrow distinction, but worth noting here.

Panel Member #8 Appropriateness of measure exclusions should be reviewed by standing committee.

1. Evidence and Performance Gap – Importance to Measure and Report

Extent to which the specific measure focus is evidence-based, important to making significant gains in healthcare quality, and improving health outcomes for a specific high-priority (high-impact) aspect of healthcare where there is variation in or overall less-than-optimal performance. ***Measures must be judged to meet all sub criteria to pass this criterion and be evaluated against the remaining criteria.***

1a. Evidence to Support the Measure Focus – See attached Evidence Submission Form

2978_Evidence_Form-637213758777646398.docx

1a.1 For Maintenance of Endorsement: Is there new evidence about the measure since the last update/submission?

Do not remove any existing information. If there have been any changes to evidence, the Committee will consider the new evidence. Please use the most current version of the evidence attachment (v7.1). Please use red font to indicate updated evidence.

Yes

1a. Evidence (subcriterion 1a)

Measure Number (*if previously endorsed*)**:** 2978

Measure Title: Hemodialysis Vascular Access: Long-term Catheter Rate

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: 4/2/2020

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*): catheter rate

☐ 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.

Several observational studies have demonstrated an association between type of vascular access used for hemodialysis and patient mortality. Long term catheter use is associated with the highest mortality risk while arteriovenous fistula use has the lowest mortality risk. Arteriovenous grafts (AVG) have been found to have a risk of death that is higher than AVF but lower than catheters.

The measure focus is the process of assessing long term catheter use at chronic dialysis facilities.

This process leads to improvement in mortality 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.

2019/2020 Submission

Several observational studies have demonstrated an association between type of vascular access used for hemodialysis and patient mortality. Long term catheter use is associated with the highest mortality risk while arteriovenous fistula use has the lowest mortality risk. Arteriovenous grafts (AVG) have been found to have a risk of death that is higher than AVF but lower than catheters.

The measure focus is the process of assessing long term catheter use at chronic dialysis facilities.

This process leads to improvement in blood stream infection / mortality 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 blood stream infection / 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.

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

2019/2020 Submission

When this measure was originally submitted for NQF endorsement, the evidence to support the measure was based largely on the National Kidney Foundation (NKF) KDOQI Clinical Practice Guideline for Vascular Access published in 2006. The NKF recently made substantial revisions to these guidelines that were released on 3/12/20. Please see:

> Lok CE, Huber TS, Lee T, et al; KDOQI Vascular Access Guideline Work Group. KDOQI clinical practice guideline for vascular access: 2019 update. Am J Kidney Dis. 2020;75(4)(suppl 2):S1-S164. https://www.ajkd.org/article/S0272-6386(19)31137-0/fulltext

The revised guidelines emphasize a patient-focused approach that recommends the development of an End Stage Kidney Disease (ESKD) Life-Plan, and urges providers to not only consider the current vascular access, but subsequent access needs as well in the context of a comprehensive evaluation of the patient's lifetime with ESKD.

Guidelines

2.1 KDOQI considers it reasonable to have an AV access (AVF or AVG) in a patient requiring HD, when consistent with their ESKD Life-Plan and overall goals of care. (Expert Opinion)

2.2 KDOQI considers it reasonable in valid clinical circumstances to use tunneled CVCs for short-term or long-term durations for incident patients, as follows (Expert Opinion):

Long-term or indefinite duration:

- Multiple prior failed AV accesses with no available options (see anatomic restrictions below)
- Valid patient preference whereby use of an AV access would severely limit QOL or achievement of life goals and after the patient has been properly informed of patient-specific risks and benefits of other potential and reasonable access options for that patient (if available)
- Limited life expectancy
- Absence of AV access creation options due to a combination of inflow artery and outflow vein problems (eg, severe arterial occlusive disease, noncorrectable central venous outflow occlusion) or in infants/children with prohibitively diminutive vessels
- Special medical circumstances

2.3 KDOQI suggests an AV access (AVF or AVG) in preference to a CVC in most incident and prevalent HD patients due to the lower infection risk associated with AV access use. (Conditional Recommendation, Low Quality of Evidence)

2.5 KDOQI suggests that if sufficient time and patient circumstances are favorable for a mature, usable AVF, such a functioning AVF is preferred to an AVG in incident HD patients due to fewer longterm vascular access events (eg, thrombosis, loss of primary patency, interventions) associated with unassisted AVF use. (Conditional Recommendation, Low Quality of Evidence)

2.6 KDOQI suggests that most incident HD patients starting dialysis with a CVC should convert to either an AVF or AVG, if possible, to reduce their risk of infection/bacteremia, infection-related hospitalizations, and adverse consequences. (Conditional Recommendation, Very Low-Moderate Quality of Evidence)

2.13 KDOQI considers it reasonable that prevalent HD patients use an AV access (AVF or AVG) in preference to a CVC, if possible, due to the association with lower vascular access–related events (eg, infection, thrombotic, and nonthrombotic complications). (Expert Opinion)

2.14 KDOQI considers it reasonable that if clinical circumstances are favorable for a mature, usable AVF, such a functioning AVF is preferred to AVG in prevalent HD patients. (Expert Opinion)

Evidence

In general, the evidence for the above guidelines has been rated as either low or moderate, with many of the guidelines relying on expert opinion. The evidence review team focused on 16 studies and noted that

bloodstream infections were significantly lower among patients who started HD with an AV fistula or AV graft versus a catheter. While three studies from 2015-2016 consistently demonstrated lower mortality with AV fistula or an AV graft compared to a catheter, the studies were considered to be of low quality with moderate risk of bias. Thus, the workgroup refrained from recommending AV fistula on the basis of lower mortality compared to catheter use, instead relying on the evidence indicating lower blood stream infections.

The new guidelines point out the potential for bias in prior studies comparing vascular access types, vascular access complications, and patient outcomes. Specifically, the workgroup notes that the differences in AV fistula and AV graft patency are uncertain, and that AV fistula complication rates in the literature may not be generalizable to all AV fistula.

Of the studies that the evidence review team for the guidelines considered when evaluating outcomes such as patient survival and access patency, only five were from 2015 or later. These are all observational studies, although some are from national registries such as USRDS or ANZDATA that accurately represent the population considered for the measure. These studies are consistent with prior work that indicates that AV fistula are associated with better patient survival when compared with dialysis catheters[1-2, 4-5], and that this is true even in older patients[5]. However, AV fistula are more likely to require additional surgeries to achieve a functional access[1] when compared to AV grafts. This is offset by AV grafts requiring more procedures to maintain patency during the first year after creation[3].

1. Woo K, Goldman DP, Romley JA. Early Failure of Dialysis Access among the Elderly in the Era of Fistula First. Clin J Am Soc Nephrol. 2015;10(10):1791–1798. doi:10.2215/CJN.09040914
2. Kasza, J., Wolfe, R., McDonald, S., Marshall, M. R., & Polkinghorne, K. R. (2016). Dialysis modality, vascular access and mortality in end-stage kidney disease: A bi-national registry-based cohort study. Nephrology, 21(10), 878-886. https://doi.org/10.1111/nep.12688
3. Leake AE, Yuo TH, Wu T, et al. Arteriovenous grafts are associated with earlier catheter removal and fewer catheter days in the United States Renal Data System population. J Vasc Surg. 2015;62(1):123-127.
4. Malas MB, Canner JK, Hicks CW, et al. Trends in incident hemodialysis access and mortality. JAMA Surgery. 2015;150(5):441-448.
5. Park HS, Kim WJ, Kim YK, et al. Comparison of outcomes with arteriovenous fistula and arteriovenous graft for vascular access in hemodialysis: a prospective cohort study. Am J Neph. 2016;43(2):120-128.

We conducted a literature review to supplement the KDOQI guidelines (literature reviewed through 2017) by using the following search in PubMed: “Arteriovenous fistula OR venous catheter AND dialysis AND published January 1, 2017 – 2020 (present).” In general, the recent articles offer additional support for the general concepts laid out in the KDOQI guidelines that AV fistula continue to be the preferred vascular access for most, but not all patients on dialysis, and that long-term catheters are associated with higher rates of infection and potentially mortality as well.

Recent literature has expanded our knowledge of vascular access in special populations, such as the elderly. One study highlights the benefit of AV fistula creation in patients over the age of 67 who start dialysis with a catheter and reports lower rates of infection and mortality after AV fistula creation relative to those who have an AV graft placed[6]. However, Hall et al point that among older adults, the cost-effectiveness of an AV fistula placed within the first month of dialysis diminishes with increasing age and lower life expectancy[7].

While patients with multiple comorbid conditions are less likely to use an AV fistula for hemodialysis vascular access, a recent study noted that after adjustment for patient characteristics there were only small differences in facility rates of AVF use except in the extremes of high or low levels of comorbidity burden[8]. This suggests that dialysis facilities with a relatively high patient comorbidity burden can achieve similar fistula rates as

facilities with healthier patients. This is further supported by geographic differences noted in AV fistula placement and maturation rates that exist even after adjustment for patient-level factors[9]. As an example of facility processes of care that can impact vascular access outcomes, dialysis facilities that have used a formalized access program were successfully able to reduce catheter rates, central line-associated bloodstream infection, and the resultant hospitalizations, mortality, and costs[10].

As noted above, the evidence review team downgraded the prior emphasis placed on the mortality benefit associated with an AV fistula. Additional studies published subsequent to their review draw similar conclusions that the survival advantage of AV fistula was likely overstated in the past[11], and that it does not appear to be related specifically to fewer access related complications[12-13]. In addition, there is growing recognition that AV fistula failure in the first year after creation is common and results in substantially higher health care costs[14]. Ultimately, additional efforts such as the Standardized Outcomes in Nephrology-Hemodialysis (SONG-HD) consensus workshop[15] may be needed to inform future vascular access measure development.

In summary, the recently revised KDOQI guidelines for vascular access continue to support AV fistula as the preferred vascular access for most patients on dialysis, although with less emphasis than in prior iterations. Long-term catheters are still viewed as the least desirable vascular access, primarily due to the increased risk of blood-stream infections, with increased recognition of certain patient characteristics and scenarios where this access type may be the most appropriate. Ultimately, dialysis facility processes of care, such as the use of a vascular access coordinator or surgeon selection, may have a greater impact on ability to reduce tunneled catheter use and create AV fistula compared to patient-level factors such as comorbidities.

References

6. Lee T, Thamer M, Zhang Q, Zhang Y, Allon M. Vascular Access Type and Clinical Outcomes among Elderly Patients on Hemodialysis. Clin J Am Soc Nephrol. 2017 Nov 7;12(11):1823-1830. doi: 10.2215/CJN.01410217. Epub 2017 Aug 10.

   BACKGROUND AND OBJECTIVES: The optimal type of initial permanent access for hemodialysis among the elderly is controversial. Duration of central venous catheter dependence, patient comorbidities, and life expectancy are important considerations in whether to place an arteriovenous fistula or graft. We used an observational study design to compare clinical outcomes in elderly patients who initiated hemodialysis with a central venous catheter and subsequently had an arteriovenous fistula or graft placed.

   DESIGN, SETTING, PARTICIPANTS, & MEASUREMENTS: We identified 9458 United States patients ages ≥67 years old who initiated hemodialysis from July 1, 2010 to June 30, 2011 with a central venous catheter and no secondary vascular access and then received an arteriovenous fistula (n=7433) or graft (n=2025) within 6 months. We evaluated key clinical outcomes during the 6 months after vascular

   access placement coincident with high rates of catheter use and used a matched propensity score analysis to examine patient survival.

   RESULTS: Central venous catheter dependence was greater in every month during the 6-month period after arteriovenous fistula versus graft placement (P<0.001). However, rates of all-cause infection-related hospitalization (adjusted relative risk, 0.93; 95% confidence interval, 0.87 to 0.99; P=0.01) and bacteremia/septicemia-related hospitalization (adjusted relative risk, 0.90; 95% confidence interval, 0.82 to 0.98; P=0.02) were lower in the arteriovenous fistula versus graft group as was the adjusted risk of death (hazard ratio, 0.76; 95% confidence interval, 0.73 to 0.80; P<0.001).

   CONCLUSIONS: Despite extended central venous catheter dependence, elderly patients initiating hemodialysis with a central venous catheter who underwent arteriovenous fistula placement within 6 months had fewer hospitalizations due to infections and a lower likelihood of death than those receiving an arteriovenous graft.

7. Hall RK, Myers ER, Rosas SE, O'Hare AM, Colón-Emeric CS. Choice of Hemodialysis Access in Older Adults: A Cost-Effectiveness Analysis. Clin J Am Soc Nephrol. 2017 Jun 7;12(6):947-954. doi: 10.2215/CJN.11631116. Epub 2017 May 18.

   BACKGROUND AND OBJECTIVES: Although arteriovenous fistulas have been found to be the most cost-effective form of hemodialysis access, the relative benefits of placing an arteriovenous fistula versus an arteriovenous graft seem to be least certain for older adults and when placed preemptively. However, older adults' life expectancy is heterogeneous, and most patients do not undergo permanent access creation until after dialysis initiation. We evaluated cost-effectiveness of arteriovenous fistula placement after dialysis initiation in older adults as a function of age and life expectancy.

   DESIGN, SETTING, PARTICIPANTS, & MEASUREMENTS: Using a hypothetical cohort of patients on incident hemodialysis with central venous catheters, we constructed Markov models of three treatment options: (1) arteriovenous fistula placement, (2) arteriovenous graft placement, or (3) continued catheter use. Costs, utilities, and transitional probabilities were derived from existing literature. Probabilistic sensitivity analyses were performed by age group (65-69, 70-74, 75-79, 80-84, and 85-89 years old) and quartile of life expectancy. Costs, quality-adjusted life-months, and incremental cost-effectiveness ratios were evaluated for up to 5 years.

   RESULTS: The arteriovenous fistula option was cost effective compared with continued catheter use for all age and life expectancy groups, except for 85-89 year olds in the lowest life expectancy quartile. The arteriovenous fistula option was more cost effective than the arteriovenous graft option for all quartiles of life expectancy among the 65- to 69-year-old age group. For older age groups, differences in cost-effectiveness between the strategies were attenuated, and the arteriovenous fistula option tended to only be cost effective in patients with life expectancy >2 years. For groups for which the arteriovenous fistula option was not cost saving, the cost to gain one quality-adjusted life-month ranged from $2294 to $14,042.

   CONCLUSIONS: Among older adults, the cost-effectiveness of an arteriovenous fistula placed within the first month of dialysis diminishes with increasing age and lower life expectancy and is not the most cost-effective option for those with the most limited life expectancy.

8. Dahlerus C, Kim S, Chen S, Segal JH. Arteriovenous Fistula Use in the United States and Dialysis Facility-Level Comorbidity Burden. Am J Kidney Dis. 2019 Nov 22:S0272-6386(19)31031-5. doi: 10.1053/j.ajkd.2019.08.023. Online ahead of print.

   RATIONALE & OBJECTIVE: Patients with multiple comorbid conditions are less likely to use an arteriovenous fistula (AVF) for hemodialysis vascular access. Some dialysis facilities have high rates of AVF placement despite having patients with many comorbid conditions. This study describes variation in facility-level use of AVFs across the facility-level burden of patient comorbid conditions.

   STUDY DESIGN: Retrospective cohort study.

   SETTING & PARTICIPANTS: Medicare patients receiving hemodialysis for 1 year or more in US dialysis facilities.

   PREDICTORS: Facility-level burden of patient comorbid conditions; patient characteristics.

   OUTCOMES: Odds of AVFs versus other access types; facility-level use of AVFs.

   ANALYTICAL APPROACH: Facility-level comorbidity burden was calculated by summing individual comorbid conditions, determining the average per patient, then defining 11 groups based on facility percentile ranking. Generalized estimating equations with a logit link were used to estimate the odds of AVF placement at the patient level. For the facility-level analysis, a generalized estimating equation model with the identity link was fit to characterize the percentage of AVF use at each facility.

   RESULTS: Overall, AVF use was 65.8% in 315,919 prevalent hemodialysis patients among 5,813 facilities. After adjustment for patient characteristics, AVF use was 0.27, 0.30, 1.05, and 1.74

percentage points lower than the median among facilities in the 61st to 70th, 71st to 80th, 81st to 90th, and 91st to 99th percentiles of comorbidity, respectively, and 0.42, 0.63, 1.34, and 1.90 percentage points higher than the median among facilities in the 31st to 40th, 21st to 30th, 11th to 20th, and 1st to 10th percentiles of comorbidity, respectively. Facilities in the greater than 99th percentile of comorbidity burden had AVF use that was 3.47 percentage points lower than the median. Facilities in the less than 1st percentile of comorbidity burden had AVF use that was 2.64 percentage points greater than the median.
LIMITATIONS: Limited to Medicare dialysis-dependent patients treated for 1 year or more.
CONCLUSIONS: After adjustment for patient characteristics, we found small differences in facility rates of AVF use except in the extremes of high or low levels of comorbidity burden. Our study demonstrates that dialysis facilities with a relatively high patient comorbidity burden can achieve similar fistula rates as facilities with healthier patients. Although high comorbidity burden does not explain low facility AVF use, additional study is needed to understand differences in AVF use rates between facilities with similar comorbidity burdens.

9. Woodside KJ, Bell S, Mukhopadhyay P, Repeck KJ, Robinson IT, Eckard AR et al. Am J Kidney Dis. 2018 Jun;71(6):793-801. doi: 10.1053/j.ajkd.2017.11.020. Epub 2018 Feb 9. Arteriovenous Fistula Maturation in Prevalent Hemodialysis Patients in the United States: A National Study.
BACKGROUND: Arteriovenous fistulas (AVFs) are the preferred form of hemodialysis vascular access, but maturation failures occur frequently, often resulting in prolonged catheter use. We sought to characterize AVF maturation in a national sample of prevalent hemodialysis patients in the United States.
STUDY DESIGN: Nonconcurrent observational cohort study.
SETTING & PARTICIPANTS: Prevalent hemodialysis patients having had at least 1 new AVF placed during 2013, as identified using Medicare claims data in the US Renal Data System.
PREDICTORS: Demographics, geographic location, dialysis vintage, comorbid conditions.
OUTCOMES: Successful maturation following placement defined by subsequent use identified using monthly CROWNWeb data.
MEASUREMENTS: AVF maturation rates were compared across strata of predictors. Patients were followed up until the earliest evidence of death, AVF maturation, or the end of 2014.
RESULTS: In the study period, 45,087 new AVFs were placed in 39,820 prevalent hemodialysis patients. No evidence of use was identified for 36.2% of AVFs. Only 54.7% of AVFs were used within 4 months of placement, with maturation rates varying considerably across end-stage renal disease (ESRD) networks. Older age was associated with lower AVF maturation rates. Female sex, black race, some comorbid conditions (cardiovascular disease, peripheral artery disease, diabetes, needing assistance, or institutionalized status), dialysis vintage longer than 1 year, and catheter or arteriovenous graft use at ESRD incidence were also associated with lower rates of successful AVF maturation. In contrast, hypertension and prior AVF placement at ESRD incidence were associated with higher rates of successful AVF maturation.
LIMITATIONS: This study relies on administrative data, with monthly recording of access use.
CONCLUSIONS: We identified numerous associations between AVF maturation and patient-level factors in a recent national sample of US hemodialysis patients. After accounting for these patient factors, we observed substantial differences in AVF maturation across some ESRD networks, indicating a need for additional study of the provider, practice, and regional factors that explain AVF maturation.

10. Rosenberry PM, Niederhaus SV, Schweitzer EJ, Leeser DB. Decreasing dialysis catheter rates by creating a multidisciplinary dialysis access program. J Vasc Access. 2018 Nov;19(6):569-572. doi: 10.1177/1129729818762977. Epub 2018 Mar 26.

INTRODUCTION: Centers for Medicare and Medicaid Services have determined that chronic dialysis units should have <12% of their patients utilizing central venous catheters for hemodialysis treatments. On the Eastern Shore of Maryland, the central venous catheter rates in the dialysis units averaged >45%. A multidisciplinary program was established with goals of decreasing catheter rates in order to decrease central line-associated bloodstream infections, decrease mortality associated with central line-associated bloodstream infection, decrease hospital days, and provide savings to the healthcare system.
METHODS: We collected the catheter rates within three dialysis centers served over a 5-year period. Using published data surrounding the incidence and related costs of central line-associated bloodstream infection and mortality per catheter day, the number of central line-associated bloodstream infection events, the costs, and the related mortality could be determined prior to and after the initiation of the dialysis access program.
RESULTS: An organized dialysis access program resulted in a 82% decrease in the number of central venous catheter days which lead to a concurrent reduction in central line-associated bloodstream infection and deaths. As a result of creating an access program, central venous catheter rates decreased from an average rate of 45% to 8%. The cost savings related to the program was calculated to be over US$5 million. The decrease in the number of mortalities is
estimated to be between 13 and 27 patients.
CONCLUSION: We conclude that a formalized access program decreases catheter rates, central line-associated bloodstream infection, and the resultant hospitalizations, mortality, and costs. Areas with high hemodialysis catheter rates should develop access programs to better serve their patient population.

11. Brown RS, Patibandla BK, Goldfarb-Rumyantzev AS. The Survival Benefit of "Fistula First, Catheter Last" in Hemodialysis Is Primarily Due to Patient Factors. J Am Soc Nephrol. 2017 Feb;28(2):645-652. doi: 10.1681/ASN.2016010019. Epub 2016 Sep 7.
    Patients needing hemodialysis are advised to have arteriovenous fistulas rather than catheters because of significantly lower mortality rates. However, disparities in fistula placement raise the possibility that patient factors have a role in this apparent mortality benefit. We derived a cohort of 115,425 patients on incident hemodialysis ≥67 years old from the US Renal Data System with linked Medicare claims to identify the first predialysis vascular access placed. We compared mortality outcomes in patients initiating hemodialysis with a fistula placed first, a catheter after a fistula placed first failed, or a catheter placed first (n=90,517; reference group). Of 21,436 patients with a fistula placed first, 9794 initiated hemodialysis with that fistula, and 8230 initiated dialysis with a catheter after failed fistula placement. The fistula group had the lowest mortality over 58 months (hazard ratio, 0.50; 95% confidence interval, 0.48 to 0.52; P<0.001), with mortality rates at 6, 12, and 24 months after initiation of 9%, 17%, and 31%, respectively, compared with 32%, 46%, and 62%, respectively, in the catheter group. However, the group initiating hemodialysis with a catheter after failed fistula placement also had significantly lower mortality rates than the catheter group had over 58 months (hazard ratio, 0.66; 95% confidence interval, 0.64 to 0.68; P<0.001), with mortality rates of 15%, 25%, and 42% at 6, 12, and 24 months, respectively. Thus, patient factors affecting fistula placement, even when patients are hemodialyzed with a catheter instead, may explain at least two thirds of the mortality benefit observed in patients with a fistula.

12. Ravani P, Quinn R, Oliver M, Robinson B, Pisoni R et al. Examining the Association between Hemodialysis Access Type and Mortality: The Role of Access Complications. Clin J Am Soc Nephrol. 2017 Jun 7;12(6):955-964. doi: 10.2215/CJN.12181116. Epub 2017 May 18.
    BACKGROUND AND OBJECTIVES: People receiving hemodialysis to treat kidney failure need a vascular access (a fistula, a graft, or a central venous catheter) to connect to the blood purification machine.

Higher rates of access complications are considered the mechanism responsible for the excess mortality observed among catheter or graft users versus fistula users. We tested this hypothesis using mediation analysis.
DESIGN, SETTING, PARTICIPANTS, & MEASUREMENTS: We studied incident patients who started hemodialysis therapy from North America, Europe, and Australasia (the Dialysis Outcomes and Practice Patterns Study; 1996-2011). We evaluated the association between access type and time to noninfectious (e.g., thrombosis) and infectious complications of the access (mediator model) and the relationship between access type and time-dependent access complications with 6-month mortality from the creation of the first permanent access (outcome model). In mediation analysis, we formally tested whether access complications explain the association between access type and mortality.
RESULTS: Of the 6119 adults that we studied (mean age =64 [SD=15] years old; 58% men; 47% patients with diabetes), 50% had a permanent catheter for vascular access, 37% had a fistula, and 13% had a graft. During the 6-month study follow-up, 2084 participants (34%) developed a noninfectious complication of the access, 542 (8.9%) developed an infectious complication, and 526 (8.6%) died. Access type predicted the occurrence of access complications; both access type and complications predicted mortality. The associations between access type and mortality were nearly identical in models excluding and including access complications (hazard ratio, 2.00; 95% confidence interval, 1.55 to 2.58 versus hazard ratio, 2.01; 95% confidence interval, 1.56 to 2.59 for catheter versus fistula, respectively). In mediation analysis, higher mortality with catheters or grafts versus fistulas was not the result of increased rates of access complications.
CONCLUSIONS: Hemodialysis access complications do not seem to explain the association between access type and mortality. Clinical trials are needed to clarify whether these associations are causal or reflect confounding by underlying disease severity.

13. Quinn RR, Oliver MJ, Devoe D, Poinen K, Kabani R, et al. J Am Soc Nephrol. 2017 Feb;28(2):613-620. doi: 10.1681/ASN.2016020151. Epub 2016 Oct 6. The Effect of Predialysis Fistula Attempt on Risk of All-Cause and Access-Related Death.

    Whether the lower risk of mortality associated with arteriovenous fistula use in hemodialysis patients is due to the avoidance of catheters or if healthier patients are simply more likely to have fistulas placed is unknown. To provide clarification, we determined the proportion of access-related deaths in a retrospective cohort study of patients aged ≥18 years who initiated hemodialysis between 2004 and 2012 at five Canadian dialysis programs. A total of 3168 patients initiated dialysis at the participating centers; 2300 met our inclusion criteria. Two investigators independently adjudicated cause of death using explicit criteria and determined whether a death was access-related. We observed significantly lower mortality in individuals who underwent a predialysis fistula attempt than in those without a predialysis fistula attempt in patients aged <65 years (hazard ratio [HR], 0.49; 95% confidence interval [95% CI], 0.29 to 0.82) and in the first 2 years of follow-up in those aged ≥65 years (HR0-24 months, 0.60; 95% CI, 0.43 to 0.84; HR24+ months, 1.83; 95% CI, 1.25 to 2.67). Sudden deaths that occurred out of hospital accounted for most of the deaths, followed by deaths due to cardiovascular disease and infectious complications. We found only 2.3% of deaths to be access-related. In conclusion, predialysis fistula attempt may associate with a lower risk of mortality. However, the excess mortality observe in patients treated with catheters does not appear to be due to direct, access-related complications but is likely the result of residual confounding, unmeasured comorbidity, or treatment selection bias.

14. Thamer M, Lee TC, Wasse H, Glickman MH, Qian J, et al. Medicare Costs Associated With Arteriovenous Fistulas Among US Hemodialysis Patients. Am J Kidney Dis. 2018 Jul;72(1):10-18. doi: 10.1053/j.ajkd.2018.01.034. Epub 2018 Mar 28.

BACKGROUND: An arteriovenous fistula (AVF) is the recommended vascular access for hemodialysis (HD). Previous studies have not examined the resources and costs associated with creating and maintaining AVFs.
STUDY DESIGN: Retrospective observational study.
SETTING & PARTICIPANTS: Elderly US Medicare patients initiating hemodialysis therapy during 2010 to 2011.
PREDICTOR: AVF primary and secondary patency and nonuse in the first year following AVF creation.
OUTCOMES: Annualized vascular access costs per patient per year.
RESULTS: Among patients with only a catheter at HD therapy initiation, only 54% of AVFs were successfully used for HD, 10% were used but experienced secondary patency loss within 1 year of creation, and 83% experienced primary patency loss within 1 year of creation. Mean vascular access costs per patient per year in the 2.5 years after AVF creation were $7,871 for AVFs that maintained primary patency in year 1, $13,282 for AVFs that experienced primary patency loss in year 1, $17,808 for AVFs that experienced secondary patency loss in year 1, and $31,630 for AVFs that were not used. Similar patterns were seen among patients with a mature AVF at HD therapy initiation and patients with a catheter and maturing AVF at HD therapy initiation. Overall, in 2013, fee-for-service Medicare paid $2.8 billion for dialysis vascular access-related services, ∼12% of all end-stage renal disease payments.
LIMITATIONS: Lack of granularity with certain billing codes.
CONCLUSIONS: AVF failure in the first year after creation is common and results in substantially higher health care costs. Compared with patients whose AVFs maintained primary patency, vascular access costs were 2 to 3 times higher for patients whose AVFs experienced primary or secondary patency loss and 4 times higher for patients who never used their AVFs. There is a need to improve AVF outcomes and reduce costs after AVF creation.

15. Andrea K Viecelli, Allison Tong, Emma O'Lone, Angela Ju, Camilla S Hanson, et al for the SONG-HD Vascular Access Workshop Investigators. Report of the Standardized Outcomes in Nephrology-Hemodialysis (SONG-HD) Consensus Workshop on Establishing a Core Outcome Measure for Hemodialysis Vascular Access Am J Kidney Dis. 71 (5), 690-700 May 2018.

    Vascular access outcomes in hemodialysis are critically important for patients and clinicians, but frequently are neither patient relevant nor measured consistently in randomized trials. A Standardized Outcomes in Nephrology-Hemodialysis (SONG-HD) consensus workshop was convened to discuss the development of a core outcome measure for vascular access. 13 patients/caregivers and 46 professionals (clinicians, policy makers, industry representatives, and researchers) attended. Participants advocated for vascular access function to be a core outcome based on the broad applicability of function regardless of access type, involvement of a multidisciplinary team in achieving a functioning access, and the impact of access function on quality of life, survival, and other access-related outcomes. A core outcome measure for vascular access required demonstrable feasibility for implementation across different clinical and trial settings. Participants advocated for a practical and flexible outcome measure with a simple actionable definition. Integrating patients' values and preferences was warranted to enhance the relevance of the measure. Proposed outcome measures for function included "uninterrupted use of the access without the need for interventions" and "ability to receive prescribed dialysis," but not "access blood flow," which was deemed too expensive and unreliable. These recommendations will inform the definition and implementation of a core outcome measure for vascular access function in hemodialysis trials.

2016 Submission

Source of Systematic Review: • **Title** • **Author** • **Date** • **Citation, including page number** • **URL**	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
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.	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)
Grade assigned to the **evidence** associated with the recommendation with the definition of the grade	The quality of evidence was not explicitly graded in the KDOQI guidelines. However, it was implicitly assessed according to the criteria outlined in the table in 1a.7.3 below. The workgroup considered the overall methodological quality, the target population (e.g. patients on dialysis), and whether the health outcome was studied directly or not. Overall, the evidence that supports the guideline was assessed as: Moderately Strong. The workgroup defined “Moderately Strong” as: Evidence is sufficient to determine effects on health outcomes in the target population, but the strength of the evidence is limited by the number, quality, or consistency of the individual 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.

Provide all other grades and definitions from the evidence grading system	(included at end of Evidence form)
Grade assigned to the **recommendation** with definition of the grade	KDOQI Guideline 2.1 was graded B, indicating moderate evidence supports the guideline. The "B" rating indicates: 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?	The 2006 Clinical Practice Guidelines for Vascular Access is an update to the original vascular access guidelines published in 1997 by the National Kidney Foundation. In the eight years that the literature review included for the update, there have been no randomized controlled trials for type of vascular access. Specifically, for the guideline used to support this measure, a total of 84 peer-reviewed publications are included in the body of evidence presented. While these are all observational studies, some are based on either national data such as the United States Renal Data System (USRDS) that includes all patients with end stage kidney disease in the US, or international data, such as the Dialysis Outcomes Practice Pattern Study (DOPPS) that provides a global perspective for US vascular access outcomes. The overall quality of evidence is moderately strong. All studies are in the target population of hemodialysis patients. Some studies have evaluated health outcomes such as patient mortality, but have limitations due to the observational nature of the design. Other studies have more rigorous design, but use surrogate outcomes such as access thrombosis.

Estimates of benefit and consistency across studies	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 Cost[1-3]: 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 catheters[4]. 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 fistulae[6-9]. Other studies have also found that use of fistulae reduces mortality and morbidity[10-12] 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
What harms were identified?	Unintended consequences of catheter avoidance strategies were not well studied at the time when the clinical practice guidelines were developed. More recently, members of the dialysis community have voiced concern that an aggressive agenda to create AVF in most all patients would lead to unnecessary surgery for some patients that have a high risk of mortality either before starting dialysis or within the first year of treatment. Despite these concerns, the overall risk associated with AV fistula creation to avoid long term catheter use are considered to be small and overshadowed by the long-term benefits outlined above for fistula use.
Identify any new studies conducted since the SR. Do the new studies change the conclusions from the SR?	Casey JR, Hanson CS, Winkelmayer WC, et al. **Patients' perspectives on hemodialysis vascular access: a systematic review of qualitative studies.** *Am J Kidney Dis. 2014 Dec;64(6):937-53. doi: 10.1053/j.ajkd.2014.06.024. Epub 2014 Aug 10*. This systematic review and thematic synthesis of qualitative studies describes patients' perspectives on vascular access initiation and maintenance in hemodialysis. 46 studies were reviewed and found that initiation of vascular access signifies kidney failure and imminent dialysis, which is emotionally confronting. Patients strive to preserve their vascular access for survival, but at the same time describe it as an agonizing reminder of their body's failings and "abnormality" of being amalgamated with a machine disrupting their identity and lifestyle. Timely education and counseling about vascular access and building patients' trust in health care providers may improve the quality of dialysis and lead to better outcomes for patients with chronic kidney disease requiring hemodialysis. Impact: Adds the patient's perspective to the discussion on vascular access options.

	Al-Jaishi AA, Oliver MJ, Thomas SM, et al. **Patency rates of the arteriovenous fistula for hemodialysis: a systematic review and meta-analysis.** *Am J Kidney Dis. 2014 Mar;63(3):464-78. doi: 10.1053/j.ajkd.2013.08.023. Epub 2013 Oct 30. Review.* This systematic review and meta-analysis reported that in recent years AVFs had a high rate of primary failure and low to moderate primary and secondary patency rates. Consideration of these outcomes is required when choosing a patient's preferred access type. Impact: Updates primary and secondary patency rates of AVF for more contemporary cohorts of dialysis patients. The lower success rates suggests that some patients may not realize the full benefits of AVF that have been previously reported in the KDOQI systematic review. Oliver MJ, Quinn RR. **Recalibrating vascular access for elderly patients.** *Clin J Am Soc Nephrol. 2014 Apr;9(4):645-7. doi: 10.2215/CJN.01560214. Epub 2014 Mar 20.* Governments in numerous jurisdictions have set targets for fistula utilization and some have tied reimbursement to attaining these targets. This creates an environment in which it is tempting to overemphasize the benefits of fistulas and the risks of catheters when discussing vascular access options with patients. Impact: Highlights that not all older patients may benefit from an AVF. Drew DA, Lok CE, Cohen JT, et al. **Vascular access choice in incident hemodialysis patients: a decision analysis.** *J Am Soc Nephrol. 2015 Jan;26(1):183-91. doi: 10.1681/ASN.2013111236. Epub 2014 Jul 25.* Decision analysis evaluating AV fistula, AV graft, and central venous catheter (CVC) strategies for patients initiating hemodialysis with a CVC, a scenario occurring in over 70% of United States dialysis patients. An AV fistula attempt strategy was found to be superior to AV grafts and CVCs in regard to mortality and cost for the majority of patient characteristic combinations, especially younger men without diabetes. Women with diabetes and elderly men with diabetes had similar outcomes, regardless of access type. Overall, the advantages of an AV fistula attempt strategy lessened considerably among older patients, particularly women with diabetes, reflecting the effect of lower AV fistula success rates and

	lower life expectancy. These results suggest that vascular access-related outcomes may be optimized by considering individual patient characteristics. Impact: Certain patient groups, such as women with diabetes, have lower reported success rates of AVF creation and may have equivalent outcomes with an AVG. Wish JB. **Catheter last, fistula not-so-first.** *J Am Soc Nephrol. 2015 Jan;26(1):5-7. doi: 10.1681/ASN.2014060594. Epub 2014 Jul 25.* The issue of vascular access choice is not as black and white as the Centers for Medicare & Medicaid Services (CMS) would like it to appear, with arteriovenous fistula (AVF) always being good or "first" and central venous catheters (CVCs) always being bad or "last." Nonetheless,CMS has instituted a quality incentive program (QIP) for dialysis providers that rewards high AVF prevalence and penalizes high CVC prevalence without regard to patient mix. For payment year 2014, vascular access constitutes 30% of the total QIP score. This may have already led to access to care issues, as some dialysis providers are refusing to accept patients with CVCs. CMS has recently given ground on this issue by renaming the "Fistula First" initiative "Fistula First Catheter Last" (FFLC) to emphasize that CVC avoidance is as important or more important than AVF use. Impact: Opinion piece on changes in the Fistula First initiative reflecting the implementation of the current NQF endorsed fistula and catheter vascular access measures in the CMS Quality Incentive Program (QIP). The empahsis of the opinion piece suggests a greater shift to catheter avoidance versus only prioritizing promotion of fistula use. Grubbs V, Wasse H, Vittinghoff E, et al. **Health status as a potential mediator of the association between hemodialysis vascular access and mortality.** *Nephrol Dial Transplant. 2014 Apr;29(4):892-8. doi: 10.1093/ndt/gft438. Epub 2013 Nov 13.* Selection of healthier patients for arteriovenous fistula (AVF) placement may explain higher observed catheter-associated mortality among elderly hemodialysis patients. A proportional hazard model was used to examine 117,277 incident hemodialysis patients aged 67-90 years from USRDS for the association of initial vascular access type and 5-year mortality after accounting for health status. Patients with catheter alone had more limited functional status (25.5 versus 10.8% of those with AVF) and 3-fold

	more prior hospital days than those with AVF (mean 18.0 versus 5.4). In a fully adjusted model including health status, mortality differences between access type were attenuated, but remained statistically significant <AVG [HR 1.18 (1.13-1.22)], catheter plus AVF [HR 1.20 (1.17-1.23)], catheter plus AVG {HR 1.38 [1.26 (1.21-1.31)]} and catheter only [HR 1.54 (1.50-1.58)], P < 0.001>.The observed attenuation in mortality differences previously attributed to access type alone suggests the existence of selection bias. Nevertheless, the persistence of an apparent survival advantage after adjustment for health status suggests that AVF should still be the access of choice for elderly individuals beginning hemodialysis until more definitive data eliminating selection bias become available. Impact: Underscores the need to adjust for patient characteristics and comorbidities when evaluating the association between vascular access type and outcomes such as mortality. Lok, Charmaine E & Foley, Robert. **Vascular access morbidity and mortality: trends of the last decade.** *Clin J Am Soc Nephrol. 2013 Jul;8(7):1213-9. doi: 10.2215/CJN.01690213.* During the past decade, clear trends in the types of incident and prevalent hemodialysis vascular access can be observed. There has been a steady increase and recent stabilizaton of patients initiating hemodialysis with a central venous catheter, representing approximately 80% of all incident accesses. There has also been a steady increase in prevalent fistula use, currently greater than 50% within 4 months of hemodialysis initiation. Patient and vascular access related morbidity and mortality are reflected in the type of vascular access used at initiation and for long-term maintenance dialysis. There is a three- to fourfold increase in risk of infectious complications in patients initiating dialysis with a catheter compared with either a fistula or graft and a sevenfold higher risk when the catheter is used as a prevalent access. Procedure rates have increased two- to threefold for all types of access. There is a significant increased risk of mortality associated with catheter use, especially within the first year of dialysis initiation. Impact: Despite longstanding KDOQI guidelines, many patients still start hemodialysis with a tunneled catheter and experience higher rates of infectious complications compared to those with an AVF. Ravani, Pietro & Palmer, Suetonia C & Oliver, Matthew J et al. **Associations between hemodialysis access type and clinical**

	outcomes: a systematic review. *J Am Soc Nephrol. 2013 Feb;24(3):465-73. doi: 10.1681/ASN.2012070643. Epub 2013 Feb 21.* Clinical practice guidelines recommend an arteriovenous fistula as the preferred vascular access for hemodialysis, but quantitative associations between vascular access type and various clinical outcomes remain controversial. This systematic review of cohort studies evaluates the associations between type of vascular access (arteriovenous fistula, arteriovenous graft, and central venous catheter) and risk for death, infection, and major cardiovascular events. 67 (62 cohort studies comprising 586,337 participants)studies were selected. In a random effects meta-analysis, compared with persons with fistulas, those individuals using catheters had higher risks for all-cause mortality (risk ratio=1.53, 95% CI=1.41-1.67), fatal infections (2.12, 1.79-2.52), and cardiovascular events (1.38, 1.24-1.54). Similarly, compared with persons with grafts, those individuals using catheters had higher risks for mortality (1.38, 1.25-1.52), fatal infections (1.49, 1.15-1.93), and cardiovascular events (1.26, 1.11-1.43). Compared with persons with fistulas, those individuals with grafts had increased all-cause mortality (1.18, 1.09-1.27) and fatal infection (1.36, 1.17-1.58), but we did not detect a difference in the risk for cardiovascular events (1.07, 0.95-1.21). The risk for bias, especially selection bias, was high. In conclusion, persons using catheters for hemodialysis seem to have the highest risks for death, infections, and cardiovascular events compared with other vascular access types, and patients with usable fistulas have the lowest risk. Impact: This study emphasizes that the body of evidence is consistent in the magnitude and direction of effect with regards to the benefits of AVF over central venous catheter. Moist, Louise M & Lok, Charmaine E & Vachharajani, Tushar J et al. **Optimal hemodialysis vascular access in the elderly patient.** *Semin Dial. 2012 Nov-Dec;25(6):640-8. doi: 10.1111/sdi.12037.* The optimal vascular access for elderly patients remains a challenge due to the difficulty balancing the benefits and risks in a population with increased comorbidity and decreased survival. Age is commonly associated with failure to mature in fistula and decreased rates of primary and secondary patency in both fistula and grafts. In the elderly, at 1 and 2 years, primary patency rates range from 43% to 74% and from 29% to 67%, respectively. Secondary patency rates at 1 and 2 years range from 56% to 82% and 44% to 67%, respectively. Cumulative fistula survival is no better than grafts survival when primary failures are included.

	Several observational studies consistently demonstrate a lower adjusted mortality among those using a fistula compared with a catheter; however, catheter use in the elderly is increasing in most countries with the exception of Japan. Both guidelines and quality initiatives do not acknowledge the trade-offs involved in managing the elderly patients with multiple chronic conditions and limited life expectancy or the value that patients place on achieving these outcomes. The framework for choice of vascular access presented in this article considers: (1) likelihood of disease progression before death, (2) patient life expectancy, (3) risks and benefits by vascular access type, and (4) patient preference. Future studies evaluating the timing and type of vascular access with careful assessments of complications, functionality, cost benefit, and patients' preference will provide relevant information to individualize and optimize care to improve morbidity, mortality, and quality of life in the elderly patient. Impact: Outlines the importance of considering patient factors in vascular access options for elderly patients. Schmidt, Rebecca J & Goldman, Richard S & Germain, Michael. **Pursuing permanent hemodialysis vascular access in patients with a poor prognosis: juxtaposing potential benefit and harm.** *Am J Kidney Dis. 2012 Dec;60(6):1023-31. doi: 10.1053/j.ajkd.2012.07.020. Epub 2012 Sep 19.* For patients with end-stage renal disease requiring hemodialysis, the native arteriovenous fistula remains the gold standard of vascular access, with tunneled cuffed central venous catheters reserved for temporary use or as a last resort in patients for whom a permanent vascular access is not possible. It is expected that most patients receiving hemodialysis will be suitable for arteriovenous fistula placement, with suitable patients defined as those: (1) for whom long-term dialysis is expected to confer benefit, (2) with vascular anatomy amenable to arteriovenous fistula placement, and (3) with progressive irreversible kidney failure who are more likely to require dialysis than to die before reaching dialysis dependence. The present article reviews considerations for vascular access decision making, focusing on older patients and those with a poor prognosis, weighing the risks and benefits of arteriovenous fistulas, arteriovenous grafts, and central venous catheters and emphasizing that in the process of vascular access decision making for such patients, medical and ethical obligations to avoid central

	venous catheters must be balanced by the obligation to do no harm. Impact: Risks and benefits of arteriovenous fistulas, relative to arteriovenous grafts, and central venous catheters need to be considered, particularly carefully in older patients and those with poor prognosis (limited life expectancy). Vassalotti, Joseph A & Jennings, William C & Beathard, Gerald A et al. **Fistula first breakthrough initiative: targeting catheter last in fistula first.** *Semin Dial. 2012 May;25(3):303-10. doi: 10.1111/j.1525-139X.2012.01069.x. Epub 2012 Apr 4.* An arteriovenous fistula (AVF) is the optimal vascular access for hemodialysis (HD), because it is associated with prolonged survival, fewer infections, lower hospitalization rates, and reduced costs. The AVF First breakthrough initiative (FFBI) has made dramatic progress, effectively promoting the increase in the national AVF prevalence since the program's inception from 32% in May 2003 to nearly 60% in 2011. Central venous catheter (CVC) use has stabilized and recently decreased slightly for prevalent patients (treated more than three months), while CVC usage in the first three months remains unacceptably high at nearly 80%. This high prevalence of CVC utilization suggests important specific improvement goals for FFBI. In addition to the current 66% AVF goal, the initiative should include specific CVC usage target(s), based on the KDOQI goal of less than 10% in patients undergoing HD for more than three months, and a substantially improved initial target from the current CVC proportion. These specific CVC targets would be disseminated through the ESRD networks to individual dialysis facilities, further emphasizing CVC avoidance in the transition from advanced CKD to chronic kidney failure, while continuing to decrease CVC by prompt conversion of CVC-based hemodialysis patients to permanent vascular access, utilizing an AVF whenever feasible. Impact: Emphasizes that catheter avoidance should receive more attention than simply increasing the proportion of patients with an AVF. Tamura, Manjula Kurella & Tan, Jane C & O'Hare, Ann M. **Optimizing renal replacement therapy in older adults: a framework for**

	making individualized decisions. *Kidney Int. 2012 Aug;82(3):261-9. doi: 10.1038/ki.2011.384. Epub 2011 Nov 16.* It is often difficult to synthesize information about the risks and benefits of recommended management strategies in older patients with end-stage renal disease since they may have more comorbidity and lower life expectancy than patients described in clinical trials or practice guidelines. In this review, we outline a framework for individualizing end-stage renal disease management decisions in older patients. The framework considers three factors: life expectancy, the risks and benefits of competing treatment strategies, and patient preferences. We illustrate the use of this framework by applying it to three key end-stage renal disease decisions in older patients with varying life expectancy: choice of dialysis modality, choice of vascular access for hemodialysis, and referral for kidney transplantation. In several instances, this approach might provide support for treatment decisions that directly contradict available practice guidelines, illustrating circumstances when strict application of guidelines may be inappropriate for certain patients. By combining quantitative estimates of benefits and harms with qualitative assessments of patient preferences, clinicians may be better able to tailor treatment recommendations to individual older patients, thereby improving the overall quality of end-stage renal disease care. Impact: An individualized approach to vascular access decisions that relies on both quantitative assessment of benefits and harms, as well as patient preference, can lead to treatement decisions that contradict practice guidelines. Ng, Leslie J & Chen, Fangfei & Pisoni, Ronald L et al. **Hospitalization risks related to vascular access type among incident US hemodialysis patients.** *Nephrol Dial Transplant. 2011 Nov;26(11):3659-66. doi: 10.1093/ndt/gfr063. Epub 2011 Mar 3.* The excess morbidity and mortality related to catheter utilization at and immediately following dialysis initiation may simply be a proxy for poor prognosis. This study examined hospitalization burden related to vascular access (VA) type among incident patients who received some predialysis care using the DOPPS patient cohort (1996-2004) who reported predialysis nephrologist care. VA utilization was assessed at baseline and throughout the first 6 months on dialysis. Poisson regression was used to estimate the risk of all-cause and cause-specific hospitalizations during the first 6 months. Among 2635 incident patients, 60% were dialyzing with a

	catheter, 22% with a graft and 18% with a fistula at baseline. Compared to fistulae, baseline catheter use was associated with an increased risk of all-cause hospitalization [adjusted relative risk (RR) = 1.30, 95% confidence interval (CI): 1.09-1.54] and graft use was not (RR = 1.07, 95% CI: 0.89-1.28). Allowing for VA changes over time, the risk of catheter versus fistula use was more pronounced (RR = 1.72, 95% CI: 1.42-2.08) and increased slightly for graft use (RR = 1.15, 95% CI: 0.94-1.41). Baseline catheter use was most strongly related to infection-related (RR = 1.47, 95% CI: 0.92-2.36) and VA-related hospitalizations (RR = 1.49, 95% CI: 1.06-2.11). These effects were further strengthened when VA use was allowed to vary over time (RR = 2.31, 95% CI: 1.48-3.61 and RR = 3.10, 95% CI: 1.95-4.91, respectively). A similar pattern was noted for VA-related hospitalizations with graft use. Among potentially healthier incident patients, hospitalization risk, particularly infection and VA-related, was highest for patients dialyzing with a catheter at initiation and throughout follow-up, providing further support to clinical practice recommendations to minimize catheter placement. Impact: Additional support for the association between catheter use and risk of hospitalization, particularly infection related hospitalizations.

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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.

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

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

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

		Methadologic Quality		
Outcome	**Population**	**Well designed and analyzed (little if any potential bias)**	**Some problems in design and/or analysis (some potential bias)**	**Poorly designed and/or analyzed (large potential bias)**
Health Outcomes	Target Population	Strong	Moderately Strong	Weak
Health Outcomes	Other than target population	Moderately Strong	Moderately Strong	Weak
Surrogate Measure	Target Population	Moderately Strong	Weak	Weak
Surrogate Measure	Other than target population	Weak	Weak	Weak

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 the 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.

1b. Performance Gap

Demonstration of quality problems and opportunity for improvement, i.e., data demonstrating:

- considerable variation, or overall less-than-optimal performance, in the quality of care across providers; and/or
- Disparities in care across population groups.

1b.1. Briefly explain the rationale for this measure *(e.g., how the measure will improve the quality of care, the benefits or improvements in quality envisioned by use of this measure)*

If a COMPOSITE (e.g., combination of component measure scores, all-or-none, any-or-none), SKIP this question and answer the composite questions.

According to data from the USRDS (based on CMS Fistula First and CROWNWeb data sources; USRDS 2018), in 2016, 80% of patients started hemodialysis with a catheter; and 69% of patients were still using catheters 90-days after starting chronic hemodialysis. Despite the persistent high use of catheters at dialysis initiation, a gradual trend towards lower long-term catheter use has been observed among prevalent maintenance HD patients in the US, declining from approximately 13.5% in 2003 to approximately 9.4% by December 2015. Additional reductions in the long-term catheter use has been achieved with rates for prevalent dialysis patients declining to 8.1% in May 2017.

Continued monitoring of chronic catheter use is needed to sustain this trend and decrease chronic catheter use. This measure is intended to be jointly reported with the Hemodialysis Vascular Access- Standardized Fistula Rate. These two vascular access quality measures, when used together, consider Arterial Venous (AV) fistula use as a positive outcome and prolonged use of a tunneled catheter as a negative outcome. With the growing recognition that some patients have exhausted options for an arteriovenous fistula, or have comorbidities that may limit the success of AVF creation, joint reporting of the measures accounts for all three vascular access options. The fistula measure adjusts for patient factors where fistula placement may be either more difficult or not appropriate and acknowledges that in certain circumstances an AV graft may be the best access option. This paired incentive structure that relies on both measures reflects consensus best practice, and supports maintenance of the gains in vascular access success achieved via the Fistula First/Catheter Last Project and ESRD Network quality improvement projects over the last decade.

United States Renal Data System. 2018 USRDS annual data report: Epidemiology of kidney disease in the United States. National Institutes of Health, National Institute of Diabetes and Digestive and Kidney Diseases, Bethesda, MD, 2018

1b.2. Provide performance scores on the measure as specified (current and over time) at the specified level of analysis*. (This is required for maintenance of endorsement. Include mean, std dev, min, max, interquartile range, scores by decile. Describe the data source including number of measured entities; number of patients; dates of data; if a sample, characteristics of the entities include.) This information also will be used to address the sub-criterion on improvement (4b1) under Usability and Use.*

Analysis of CROWNWeb data from January 2018- December 2018 indicated the facility-level mean percentage of patient-months with a long-term catheter was 12.4% (SD=7.3%). Distribution: Min=0%, 1st quartile=7.8%, median=11.2%, 3rd quartile=15.4%, Max=89.9%.

Information about the data used in these analyses can be found under “Scientific Acceptability”.

1b.3. If no or limited performance data on the measure as specified is reported in 1b2, then provide a summary of data from the literature that indicates opportunity for improvement or overall less than optimal performance on the specific focus of measurement.

N/A

1b.4. Provide disparities data from the measure as specified (current and over time) by population group, e.g., by race/ethnicity, gender, age, insurance status, socioeconomic status, and/or disability. *(This is required for maintenance of endorsement. Describe the data source including number of measured entities; number of*

patients; dates of data; if a sample, characteristics of the entities included.) For measures that show high levels of performance, i.e., "topped out", disparities data may demonstrate an opportunity for improvement/gap in care for certain sub-populations. This information also will be used to address the sub-criterion on improvement (4b1) under Usability and Use.

As this measure is not risk adjusted, the analysis results and interpretation for the SDS/SES factors are included only in the response to question 1b.4 (Disparities) in the submission form. Section 2b3.4b does not apply to this measure.

Using data from January-December 2018, age, sex, race, ethnicity, dialysis vintage, employment status, Medicare coverage, and Area Deprivation Index (ADI) were evaluated in a logistic regression model for long-term catheter use. Data on patient level SDS/SES factors were obtained from Medicare claims and administrative data; zip code level data for the Area Deprivation Index (ADI) are obtained from Census data (2009-2013), based on patient zip-code.

Age, sex, ethnicity, dialysis vintage, and employment status are statistically significant predictors for odds of long-term catheter use. Females had a 44% higher odds of having a long-term catheter; younger age (18-24 years) and age 25-59 were associated with higher odds of long-term catheter use (84%, and 18% respectively) compared to patients 60-75 years of age. Hispanics had lower odds of having a long-term catheter (compared to non-Hispanics). Neither dual-eligible status nor area level deprivation (ADI) were statistically significantly associated with odds of long-term catheter use.

The results below show the odds ratios for patient- and area-level variables based on a logistic regression model for long-term catheter use (at least three months) that included these variables.

Age:

For the 18-<25 age group, the Odds Ratio (95% CI) is 1.84 (1.41, 2.40), P-value is <0.001.

For the 25-<60 age group, the Odds Ratio (95% CI) is 1.18 (1.12, 1.25), P-value is <0.001.

The 60-<75 age group was used as the reference group.

For the 75+ age group, the Odds Ratio (95% CI) is 1.06 (0.99, 1.13), P-value is 0.097.

Sex:

For Female: the Odds Ratio (95% CI) is 1.44 (1.37, 1.51), P-value is <0.001.

Male was used as the reference group.

Race:

White was used as the reference group.

For Black: the Odds Ratio (95% CI) is 1.00 (0.93, 1.07), P-value is 0.972.

For Other race: the Odds Ratio (95% CI) is 0.85 (0.76, 0.96), P-value is 0.008.

Ethnicity:

For Hispanic: the Odds Ratio (95% CI) is 0.80 (0.73, 0.87), P-value is <0.001.

Non-Hispanic was used as the reference group.

Employment Status:

Employed was used as the reference group.

For Unemployed: The Odds Ratio (95% CI) is 1.15 (1.07, 1.25), and the P-value is <0.001.

For Other: The Odds Ratio (95% CI) is 1.21 (1.13, 1.30), and the P-value is <.001.

Medicare Coverage:

Dual eligibility: the Odds Ratio (95% CI) is 1.04 (0.99, 1.09), and the P-value is 0.154.

Non-Dual eligibility was used as the reference group.

ADI (zipcode-level):

National percentile ADI score: The Odds Ratio (95% CI) is 1.00 (1.00, 1.00), and the P-value is 0.704.

1b.5. If no or limited data on disparities from the measure as specified is reported in 1b.4, then provide a summary of data from the literature that addresses disparities in care on the specific focus of measurement. Include citations. Not necessary if performance data provided in 1b.4

N/A

2. Reliability and Validity—Scientific Acceptability of Measure Properties

Extent to which the measure, as specified, produces consistent (reliable) and credible (valid) results about the quality of care when implemented. ***Measures must be judged to meet the sub criteria for both reliability and validity to pass this criterion and be evaluated against the remaining criteria.***

2a.1. Specifications The measure is well defined and precisely specified so it can be implemented consistently within and across organizations and allows for comparability. eMeasures should be specified in the Health Quality Measures Format (HQMF) and the Quality Data Model (QDM).

De.5. Subject/Topic Area *(check all the areas that apply):*

Renal, Renal : End Stage Renal Disease (ESRD)

De.6. Non-Condition Specific*(check all the areas that apply):*

De.7. Target Population Category *(Check all the populations for which the measure is specified and tested if any):*

Populations at Risk

S.1. Measure-specific Web Page *(Provide a URL link to a web page specific for this measure that contains current detailed specifications including code lists, risk model details, and supplemental materials. Do not enter a URL linking to a home page or to general information.)*

N/A

S.2a. If this is an eMeasure, HQMF specifications must be attached. Attach the zipped output from the eMeasure authoring tool (MAT) - if the MAT was not used, contact staff. (Use the specification fields in this online form for the plain-language description of the specifications)

This is not an eMeasure **Attachment:**

S.2b. Data Dictionary, Code Table, or Value Sets *(and risk model codes and coefficients when applicable) must be attached. (Excel or csv file in the suggested format preferred - if not, contact staff)*

Attachment **Attachment:** 2978_Data_Dictionary_Code_Table.xlsx

S.2c. Is this an instrument-based measure (i.e., data collected via instruments, surveys, tools, questionnaires, scales, etc.)? Attach copy of instrument if available.

No, this is not an instrument-based measure **Attachment:**

S.2d. Is this an instrument-based measure (i.e., data collected via instruments, surveys, tools, questionnaires, scales, etc.)? Attach copy of instrument if available.

Not an instrument-based measure

S.3.1. For maintenance of endorsement: Are there changes to the specifications since the last updates/submission. If yes, update the specifications for S1-2 and S4-22 and explain reasons for the changes in S3.2.

No

S.3.2. <u>For maintenance of endorsement,</u> please briefly describe any important changes to the measure specifications since last measure update and explain the reasons.

No significant changes have been made to the measures specifications.

S.4. Numerator Statement *(Brief, narrative description of the measure focus or what is being measured about the target population, i.e., cases from the target population with the target process, condition, event, or outcome) DO NOT include the rationale for the measure.*

<u>IF an OUTCOME MEASURE</u>, state the outcome being measured. Calculation of the risk-adjusted outcome should be described in the calculation algorithm (S.14).

The numerator is the number of adult patient-months in the denominator who were on maintenance hemodialysis using a catheter continuously for three months or longer as of the last hemodialysis session of the reporting month.

S.5. Numerator Details *(All information required to identify and calculate the cases from the target population with the target process, condition, event, or outcome such as definitions, time period for data collection, specific data collection items/responses, code/value sets – Note: lists of individual codes with descriptors that exceed 1 page should be provided in an Excel or csv file in required format at S.2b)*

<u>IF an OUTCOME MEASURE,</u> describe how the observed outcome is identified/counted. Calculation of the risk-adjusted outcome should be described in the calculation algorithm (S.14).

The number of patient-months with a long-term catheter in use. Long-term catheter use is defined as using a catheter, at the same facility, for at least three consecutive complete months as of the last day of the reporting month.

Vascular access type for the measure is obtained from CROWNWeb only (representative of all ESRD dialysis patients).

For a given month, if any of the following CROWNWeb "Access Type IDs" (16,18,19,20,21,"·") has been recorded, a catheter is considered in use. If a catheter has been observed for three consecutive months (i.e., in the reporting month and the immediate two preceding months) at the same facility, the reporting month is counted in the numerator. Access Type ID "16" represents AV Fistula combined with a Catheter, "18" represents AV Graft combined with a Catheter, "19" represents Catheter only, "20" represents Port access only, "21" represents other/unknown, and "·" represents missing. If a patient changes dialysis facilities, the counting of the three consecutive complete months restarts at the new facility.

We count patients with missing vascular access type in both the denominator and the numerator. Therefore missing vascular access type is counted as a catheter.

S.6. Denominator Statement *(Brief, narrative description of the target population being measured)*

All patients at least 18 years old as of the first day of the reporting month who are determined to be maintenance hemodialysis patients (in-center and home HD) for the complete reporting month at the same facility.

When used for public reporting, the measure calculation will be restricted to facilities with at least 11 patients in the reporting month. This restriction is required to ensure patients cannot be identified due to small cell size.

S.7. Denominator Details *(All information required to identify and calculate the target population/denominator such as definitions, time period for data collection, specific data collection items/responses, code/value sets – Note: lists of individual codes with descriptors that exceed 1 page should be provided in an Excel or csv file in required format at S.2b.)*

<u>IF an OUTCOME MEASURE</u>, describe how the target population is identified. Calculation of the risk-adjusted outcome should be described in the calculation algorithm (S.14).

For each patient, we identify the dialysis provider at each month using a combination of Medicare-paid dialysis claims, the Medical Evidence Form (Form CMS-2728), and data from CROWNWeb. These sources are used to identify patients that are receiving in-center or home hemodialysis for the entire reporting month. Patients are required to have been treated by the same facility for the complete month in order to be assigned to that facility for the reporting month.

To be included in the denominator for a particular reporting month, the patient must be receiving home or in-center hemodialysis for the complete reporting month at the facility, and be at least 18 years old as of the first day of the month.

The monthly patient count at a facility includes all eligible prevalent and incident patients. The number of patient-months over a time period is the sum of patients reported for the months covered by the time period. An individual patient may contribute up to 12 patient-months per year.

S.8. Denominator Exclusions *(Brief narrative description of exclusions from the target population)*

Exclusions that are implicit in the denominator definition include:

• Pediatric patients (<18 years old)

• Patients on Peritoneal Dialysis

• Patient-months on in-center or home hemodialysis for less than a complete reporting month at the same facility

In addition, the following exclusions are applied to the denominator:

Patients with a catheter that have limited life expectancy:

• Patients under hospice care in the current reporting month

• Patients with metastatic cancer in the past 12 months

• Patients with end stage liver disease in the past 12 months

• Patients with coma or anoxic brain injury in the past 12 months

S.9. Denominator Exclusion Details *(All information required to identify and calculate exclusions from the denominator such as definitions, time period for data collection, specific data collection items/responses, code/value sets – Note: lists of individual codes with descriptors that exceed 1 page should be provided in an Excel or csv file in required format at S.2b.)*

Determination of peritoneal dialysis treatment modality is derived from a combination of Medicare-paid dialysis claims, the Medical Evidence Form (Form CMS-2728), and data from CROWNWeb. These sources also determine patient assignment to the facility. Patients not treated by the facility for the entire month are excluded for that reporting month.

The patient's age is determined by subtracting the patient's date of birth from the first day of the reporting month. Patients that are < 18 years old as of the first day of the reporting month are excluded.

For the exclusion of catheter patients with limited life expectancy, catheter use in the reporting month is defined as the CROWNWeb "Access Type ID" having any of the following values: (16,18,19,20,21,"·"), where Access_Type_ID "16" represents AV Fistula combined with a Catheter, "18" represents AV Graft combined with a Catheter, "19" represents Catheter only, "20" represents Port access only, "21" represents other/unknown, and "·" represents missing.

Hospice status is determined from a separate CMS file that contains final action claims submitted by Hospice providers. Once a beneficiary elects Hospice, all Hospice related claims will be found in this file, regardless if the beneficiary is in Medicare fee-for-service or in a Medicare managed care plan. Patients are identified as receiving hospice care if they have any final action claims submitted to Medicare by hospice providers in the current month. If the patient did not have Hospice claims in the preceding 12 months of Hospice claims data, we assume this patient was not receiving hospice care in that reporting month.

Diagnoses of metastatic cancer, end stage liver disease, or coma in the past 12 months were determined from Medicare claim types. Medicare claims include inpatient hospitalizations, outpatient claims (including dialysis claims), and physician supplier claims. Claims from providers, such as laboratories, that report diagnosis codes when testing for the presence of a condition are excluded. A detailed list of ICD-10 diagnostic codes used to identify these comorbidities is included in the attached data dictionary code table (excel file). If the patient had missing comorbidity values in the preceding 12 months of Medicare claims, we assume this patient did not have the comorbidity in that reporting month.

S.10. Stratification Information *(Provide all information required to stratify the measure results, if necessary, including the stratification variables, definitions, specific data collection items/responses, code/value sets, and the risk-model covariates and coefficients for the clinically-adjusted version of the measure when appropriate – Note: lists of individual codes with descriptors that exceed 1 page should be provided in an Excel or csv file in required format with at S.2b.)*

N/A

S.11. Risk Adjustment Type (Select type. Provide specifications for risk stratification in measure testing attachment)

No risk adjustment or risk stratification

If other:

S.12. Type of score:

Rate/proportion

If other:

S.13. Interpretation of Score *(Classifies interpretation of score according to whether better quality is associated with a higher score, a lower score, a score falling within a defined interval, or a passing score)*

Better quality = Lower score

S.14. Calculation Algorithm/Measure Logic (*Diagram or describe the calculation of the measure score as an ordered sequence of steps including identifying the target population; exclusions; cases meeting the target process, condition, event, or outcome; time period for data, aggregating data; risk adjustment; etc.)*

See calculation flowchart in Appendix.

S.15. Sampling *(If measure is based on a sample, provide instructions for obtaining the sample and guidance on minimum sample size.)*

IF an instrument-based performance measure (e.g., PRO-PM), identify whether (and how) proxy responses are allowed.

N/A

S.16. Survey/Patient-reported data *(If measure is based on a survey or instrument, provide instructions for data collection and guidance on minimum response rate.)*

Specify calculation of response rates to be reported with performance measure results.

N/A

S.17. Data Source *(Check ONLY the sources for which the measure is SPECIFIED AND TESTED).*

If other, please describe in S.18.

Claims, Registry Data

S.18. Data Source or Collection Instrument *(Identify the specific data source/data collection instrument (e.g. name of database, clinical registry, collection instrument, etc., and describe how data are collected.)*

IF instrument-based, identify the specific instrument(s) and standard methods, modes, and languages of administration.

Data are derived from an extensive national ESRD patient database, which is primarily based on CROWNWeb facility-reported clinical and administrative data (including CMS-2728 Medical Evidence Form, CMS-2746 Death Notification Form, and CMS-2744 Annual Facility Survey Form and patient tracking data), the Renal Management Information System (REMIS), the Medicare Enrollment Database (EDB), and Medicare claims data. In addition the database includes transplant data from the Scientific Registry of Transplant Recipients (SRTR), and data from the Nursing Home Minimum Dataset, the Quality Improvement Evaluation System (QIES) Business Intelligence Center (QBIC) (which includes Provider and Survey and Certification data from Automated Survey Processing Environment (ASPEN)), and the Dialysis Facility Compare (DFC).

The database is comprehensive for Medicare patients not enrolled in Medicare Advantage. Medicare Advantage patients are included in all sources but their Medicare payment records are limited to inpatient claims. Non-Medicare patients are included in all sources except for the Medicare payment records. Tracking by dialysis provider and treatment modality is available for all patients including those with only partial or no Medicare coverage.

CROWNWeb is the data source for establishing the vascular access type used to determine the numerator.

S.19. Data Source or Collection Instrument *(available at measure-specific Web page URL identified in S.1 OR in attached appendix at A.1)*

No data collection instrument provided

S.20. Level of Analysis *(Check ONLY the levels of analysis for which the measure is SPECIFIED AND TESTED)*

Facility

S.21. Care Setting *(Check ONLY the settings for which the measure is SPECIFIED AND TESTED)*

Other

If other: Dialysis Facility

S.22. <u>COMPOSITE Performance Measure</u> - Additional Specifications *(Use this section as needed for aggregation and weighting rules, or calculation of individual performance measures if not individually endorsed.)*

N/A

2. Validity – See attached Measure Testing Submission Form

2978_Testing_form-637139105706828256.docx

2.1 <u>For maintenance of endorsement</u>

Reliability testing: If testing of reliability of the measure score was not presented in prior submission(s), has reliability testing of the measure score been conducted? If yes, please provide results in the Testing attachment. Please use the most current version of the testing attachment (v7.1). Include information on all testing conducted (prior testing as well as any new testing); use red font to indicate updated testing.

Yes

2.2 <u>For maintenance of endorsement</u>

Has additional empirical validity testing of the measure score been conducted? If yes, please provide results in the Testing attachment. Please use the most current version of the testing attachment (v7.1). Include information on all testing conducted (prior testing as well as any new testing); use red font to indicate updated testing.

Yes

2.3 <u>For maintenance of endorsement</u>

Risk adjustment: For outcome, resource use, cost, and some process measures, risk-adjustment that includes social risk factors is not prohibited at present. Please update sections 1.8, 2a2, 2b1,2b4.3 and 2b5 in the Testing attachment and S.140 and S.11 in the online submission form. NOTE: These sections must be updated even if

social risk factors are not included in the risk-adjustment strategy. You MUST use the most current version of the Testing Attachment (v7.1) -- older versions of the form will not have all required questions.

Yes - Updated information is included

Measure Testing (subcriteria 2a2, 2b1-2b6)

Measure Number (*if previously endorsed*)**:** Click here to enter NQF number

Measure Title: Hemodialysis Vascular Access: Long-term Catheter Rate

Date of Submission: 1/5/2020

Type of Measure:

☐ Outcome (*including PRO-PM*)	☐ Composite – ***STOP – use composite testing form***
☒ Intermediate Clinical Outcome	☐ Cost/resource
☐ Process *(including Appropriate Use)*	☐ Efficiency
☐ Structure	

1. DATA/SAMPLE USED FOR ALL TESTING OF THIS MEASURE

Often the same data are used for all aspects of measure testing. In an effort to eliminate duplication, the first five questions apply to all measure testing. If there are differences by aspect of testing,(e.g., reliability vs. validity) be sure to indicate the specific differences in question 1.7.

1.1. What type of data was used for testing? (*Check all the sources of data identified in the measure specifications and data used for testing the measure. Testing must be provided for all the sources of data specified and intended for measure implementation.* ***If different data sources are used for the numerator and denominator, indicate N [numerator] or D [denominator] after the checkbox.***)

Measure Specified to Use Data From: (***must be consistent with data sources entered in S.17***)	**Measure Tested with Data From:**
☐ abstracted from paper record	☐ abstracted from paper record
☒ claims	☒ claims
☒ registry	☒ registry
☐ abstracted from electronic health record	☐ abstracted from electronic health record
☐ eMeasure (HQMF) implemented in EHRs	☐ eMeasure (HQMF) implemented in EHRs
☐ other: Click here to describe	☐ other: Click here to describe

1.2. If an existing dataset was used, identify the specific dataset (*the dataset used for testing must be consistent with the measure specifications for target population and healthcare entities being measured; e.g., Medicare Part A claims, Medicaid claims, other commercial insurance, nursing home MDS, home health OASIS, clinical registry*).

National CROWNWeb data from January 2014-December 2014 and Medicare claims data from January 2013 – December 2014.

2019 Submission

National CROWNWeb data from January 2018-December 2018 and Medicare claims data from January 2017 – December 2018.

1.3. What are the dates of the data used in testing? January 2013-December 2014

2019 Submission

January 2017-December 2018.

1.4. What levels of analysis were tested? (*testing must be provided for all the levels specified and intended for measure implementation, e.g., individual clinician, hospital, health plan*)

Measure Specified to Measure Performance of: (***must be consistent with levels entered in item S.20***)	**Measure Tested at Level of:**
☐ individual clinician	☐ individual clinician
☐ group/practice	☐ group/practice
☒ hospital/facility/agency	☒ hospital/facility/agency
☐ health plan	☐ health plan
☐ other: Click here to describe	☐ other: Click here to describe

1.5. How many and which measured entities were included in the testing and analysis (by level of analysis and data source)? (*identify the number and descriptive characteristics of measured entities included in the analysis (e.g., size, location, type); if a sample was used, describe how entities were selected for inclusion in the sample*)

Patients on both home and in-center hemodialysis during the last HD treatment of the month from January 2014-December 2014 were included in the analyses. The number of facilities per month ranged from 5,736-5,871 and the total number of patient-months ranged from 344,945- 363,257.

Public reporting of this measure on DFC or in the ESRD QIP would be restricted to facilities with at least 11 eligible patients throughout the year for the measure. We have applied this restriction to all the reliability and validity testing reported here.

2019 Submission

Patients on either home or in-center hemodialysis during the last HD treatment of the month from January 2018-December 2018 were included in the analyses. The number of facilities per month ranged from 6,673-6,825 and the total number of patients per month ranged from 416,980- 424,441.

Public reporting of this measure on DFC or in the ESRD QIP would be restricted to facilities with at least 11 eligible patients throughout the reporting period for the measure. We have applied this restriction to all the reliability and validity testing reported here.

1.6. How many and which patients were included in the testing and analysis (by level of analysis and data source)? (*identify the number and descriptive characteristics of patients included in the analysis (e.g., age, sex, race, diagnosis); if a sample was used, describe how patients were selected for inclusion in the sample*)

There were a total of 4,274,619 eligible patient-months. Among those patient-months over the whole year, the average age was 62.7 years, 43.79% of patient-months were female, 56.27% were white, 37.05% were black, 6.68% reported race as "other", 18.41% were Hispanic and 46.37% had type II diabetes as the primary cause of ESRD.

2019 Submission

There were a total of 5,068,460 eligible patient-months. Among those patient-months over the reporting period, the average age was 63.3 years, 42.61% were female, 56.86% were white, 35.68% were black, 7.46% reported race as "other", 19.01% were Hispanic and 47.31% had type II diabetes as the primary cause of ESRD.

1.7. If there are differences in the data or sample used for different aspects of testing (e.g., reliability, validity, exclusions, risk adjustment), identify how the data or sample are different for each aspect of testing reported below.

N/A

1.8 What were the social risk factors that were available and analyzed? For example, patient-reported data (e.g., income, education, language), proxy variables when social risk data are not collected from each patient (e.g. census tract), or patient community characteristics (e.g. percent vacant housing, crime rate) which do not have to be a proxy for patient-level data.

Patient level:

- Employment status 6 months prior to ESRD
- Race
- Sex
- Ethnicity
- Medicare coverage*

**Assessed at a specific time point (e.g., at the reporting month). Medicare coverage in model was defined as:*

1. Medicare as primary and Medicaid

2. Medicare as primary and NO Medicaid

3. Medicare as secondary or Medicare HMO (e.g. Medicare Advantage)

4. Non-Medicare/missing

Data on patient level SDS/SES factors obtained from Medicare claims and administrative data.

ZIP code level – Area Deprivation Index (ADI) elements from Census data:

- Unemployment rate (%)
- Median family income
- Income disparity
- Families below the poverty level (%)
- Single-parent households with children <18 years old (%)

- Home ownership rate (%)
- Median home value
- Median monthly mortgage
- Median gross rent
- Population (aged 25+) with <9 years of education (%)
- Population (aged 25+) without high school diploma (%)

NOTE: As this measure is not risk adjusted, the analysis results and interpretation for the above SDS factors are included in the response to question **1b.4** (Disparities) in the submission form.

2019 Submission

Patient level:

- Employment status 6 months prior to ESRD
- Sex
- Race
- Ethnicity
- Medicare dual eligible
- ZIP code level – Area Deprivation Index (ADI) from Census data (2009-2013). Based on patient zip-code.

Data on patient level SDS/SES factors obtained from Medicare claims and administrative data.

NOTE: As this measure is not risk adjusted, the analysis results and interpretation for the above SDS/SES factors are included only in the response to question **1b.4** (Disparities) in the submission form. Section 2b3.4b does not apply to this measure.

2a2. RELIABILITY TESTING

***Note**: If accuracy/correctness (validity) of data elements was empirically tested, separate reliability testing of data elements is not required – in 2a2.1 check critical data elements; in 2a2.2 enter "see section 2b2 for validity testing of data elements"; and skip 2a2.3 and 2a2.4.*

2a2.1. What level of reliability testing was conducted? (*may be one or both levels*)

☐ **Critical data elements used in the measure** (*e.g., inter-abstractor reliability; data element reliability must address ALL critical data elements*)

☒ **Performance measure score** (e.g., *signal-to-noise analysis*)

2a2.2. For each level checked above, describe the method of reliability testing and what it tests (*describe the steps—do not just name a method; what type of error does it test; what statistical analysis was used*)

We used January 2014 – December 2014 CROWNWeb data to calculate facility-level annual performance scores. The NQF-recommended approach for determining measure reliability is a one-way analysis of variance (ANOVA), in which the between-facility variation (σ_b^2) and the within-facility variation ($\sigma_{t,w}^2$) in the measure is determined. The inter-unit reliability (IUR) measures the proportion of the total variation of a measure (i.e., $\sigma_b^2 + \sigma_{t,w}^2$) that is attributable to the between-facility variation, the true signal reflecting the differences across facilities. We assessed reliability by calculating inter-unit reliability (IUR) for the annual performance scores. If the measure were a simple average across individuals in the facility, the usual ANOVA approach would be

used. The yearly based measure, however, is not a simple average and we instead estimate the IUR using a bootstrap approach, which uses a resampling scheme to estimate the within facility variation that cannot be directly estimated by ANOVA. A small IUR (near 0) reveals that most of the variation of the measures between facilities is driven by random noise, indicating the measure would not be a good characterization of the differences among facilities, whereas a large IUR (near 1) indicates that most of the variation between facilities is due to the real difference between facilities.

Here we describe our approach to calculating IUR. Let $T_1,\ldots,T_N$ be the annual catheter rate for N facilities. To generate re-sampled data, we randomly draw patients from the national population B times (we set B=100). Using each re-sampled dataset, for the ith facility, we calculate an annual catheter rate ($T^*_{i,1},\ldots, T^*_{i,B}$) and their sample variance (S_i^*). From this it can be seen that

$$s^2_{t,w} = \frac{\sum_{i=1}^{N}\left[(n_i - 1)S_i^{*2}\right]}{\sum_{i=1}^{N}(n_i - 1)}$$

is a bootstrap estimate of the within-facility variance in the catheter rate, where n_i is the number of subjects in the ith facility. Calling on formulas from the one-way ANOVA, the total variation in the annual catheter rate (i.e., $\sigma_b^2 + \sigma^2_{t,w}$) can be estimated by

$$s_t^2 = \frac{1}{n'(N-1)}\sum_{i=1}^{N} n_i(T_i - \bar{T})^2$$

where the overall weighted average of catheter rate is $\bar{T} = \sum n_i T_i / \sum n_i$, and

$$n' = \frac{1}{N-1}\left(\sum n_i - \sum n_i^2 \Big/ \sum n_i\right)$$

is approximately the average facility size (number of patients per facility). Thus, the IUR = $\sigma_b^2 / (\sigma_b^2 + \sigma^2_{t,w})$ can be estimated by $(s_t^2 - s^2_{t,w})/s_t^2$.

The reliability calculation only included facilities with at least 11 patients during the entire year.

2019 Submission

The methodology described above is being applied to calculate IUR for this submission, calculated with 2018 data.

2a2.3. For each level of testing checked above, what were the statistical results from reliability testing? (e.*g., percent agreement and kappa for the critical data elements; distribution of reliability statistics from a signal-to-noise analysis*)

The IUR is 0.765, which indicates that 76.5% of the variation in the annual long-term catheter rate can be attributed to between-facility differences in performance (signal) and about 23.5% to the within-facility variation (noise).

2019 Submission

The IUR is 0.76, which indicates that 76% of the variation in the annual long-term catheter rate can be attributed to between-facility differences in performance (signal) and 24% to the within-facility variation (noise).

2a2.4 What is your interpretation of the results in terms of demonstrating reliability? (i.*e., what do the results mean and what are the norms for the test conducted?*)

The result of IUR testing suggests a high degree of reliability.

2019 Submission

The result of IUR testing suggests a high degree of reliability.

2b1. VALIDITY TESTING

2b1.1. What level of validity testing was conducted? (*may be one or both levels*)

☐ **Critical data elements** (*data element validity must address ALL critical data elements*)

☒ **Performance measure score**

☒ **Empirical validity testing**

☒ **Systematic assessment of face validity of performance measure score as an indicator** of quality or resource use (*i.e., is an accurate reflection of performance on quality or resource use and can distinguish good from poor performance*) **NOTE**: Empirical validity testing is expected at time of maintenance review; if not possible, justification is required.

2b1.2. For each level of testing checked above, describe the method of validity testing and what it tests (*describe the steps—do not just name a method; what was tested, e.g., accuracy of data elements compared to authoritative source, relationship to another measure as expected; what statistical analysis was used)*

Validity was assessed using Poisson regression models to measure the association between facility level quintiles of performance scores and the 2014 Standardized Mortality Ratio (SMR, NQF 0369) and 2014 Standardized Hospitalization Ratio (SHR, NQF 1463). Facility-level performance scores were divided into quintiles (Q1 to Q5), and the relative risk (RR) of mortality (and hospitalization, separately) was calculated for each quintile, using the combined Q1 and Q2 as the reference group. Thus, a RR>1.0 would indicate a higher relative risk of mortality or hospitalization, compared to the lowest performance score quintiles.

In 2015 a vascular access TEP was convened to provide input on the development of access measures, and specifically input on exclusions for both catheter and fistula measures, and for fistula, risk adjustment factors to be considered. The TEP felt that minimizing catheter use is paramount and that while catheters may potentially be acceptable for some patients, they addressed this through identifying patient level exclusion criteria rather than risk adjustment. The candidate catheter measure was reviewed and validated by the Technical Expert Panel (TEP) in 2015.

2019 Submission

Validity was assessed using Poisson regression models to measure the association between facility level quintiles of performance scores and the 2018 Standardized Mortality Ratio (SMR, NQF 0369) and 2018 Standardized Hospitalization Ratio (SHR, NQF 1463). Facility-level performance scores were divided into quintiles (Q1 to Q5), and the relative risk (RR) of mortality (and hospitalization, separately) was calculated for each quintile, using the combined Q1 and Q2 as the reference group. Thus, a RR>1.0 would indicate a higher relative risk of mortality or hospitalization, compared to the lowest performance score quintiles.

- SMR: We expect a positive association with SMR since the inability to successfully create a surgical access may represent lack of a robust process to coordinate care outside of the dialysis facility. Long-term catheter use is also associated with higher risk of infection which may increase the risk of a life

threatening infection or other poor outcomes that place patients at higher risk of mortality. Higher rates of facility level long-term catheter will be positively associated with SMR.

- SHR: We expect a positive association. Facilities with higher percentages of patients with a long-term catheter may not have robust process to coordinate care outside of the dialysis facility. Long-term catheter use potentially increases the risk for patients at such facilities going to hospital due to infections or other acute clinical events. Higher rates of facility level long-term catheters will be positively associated with SHR.

The face validity form the 2015 TEP described in the previous submission also carries forward for this submission.

2b1.3. What were the statistical results from validity testing? (*e.g., correlation; t-test*)

Quintiles of the performance scores were defined as follows:

Q1*: 0.0%-<6.24%

Q2*: 6.24%-<9.12%

Q3: 9.12-<12.00%

Q4: 12.00%-<16.21%

Q5: 16.21%-<58.16%

*Q1 and Q2 as Reference

Results from the Poisson model indicated that the percent of patient-months with a long-term catheter was significantly associated with the risks of mortality and hospitalization.

For the 2014 SMR, the relative risk of mortality increased as the performance measure quintile increased from the reference group (combined Q1 and Q2). For quintile 3, RR=1.03 (95% CI: 1.01, 1.05; p=0.006), quintile 4, RR=1.03 (95% CI: 1.01, 1.05; p=0.008), and quintile 5, RR=1.09 (95% CI: 1.07, 1.12; p<0.001).

Similarly for the 2014 SHR, the relative risk of hospitalization increased as the performance measure quintile increased from the reference group (combined Q1 and Q2). For quintile 3, RR=1.08 (95% CI: 1.08, 1.08; p<0.001), quintile 4, RR=1.10 (95% CI: 1.10, 1.10; p<0.001), and quintile 5, RR=1.16 (95% CI: 1.15, 1.16; p<0.001).

2019 Submission

Cut-points for the quintiles of the performance scores were defined as follows:

Q1*: 6.99%

Q2*: 9.78%

Q3: 12.71%

Q4: 16.85%

Q5: 89.89%

*Q1 and Q2 as Reference

Results from the Poisson model indicated that the percent of patient-months with a long-term catheter was significantly associated with the risks of mortality and hospitalization.

For the 2018 SMR, the relative risk of mortality showed statistically significant increases as the performance measure quintile increased from the reference group (combined Q1 and Q2) to quintile 5. For quintile 3, RR=1.03 (95% CI: 1.01, 1.05; p=0.004), quintile 4, RR=1.02 (95% CI: 1.00, 1.04; p=0.063), and quintile 5, RR=1.08 (95% CI: 1.05, 1.10; p<0.001).

Similarly for the 2018 SHR, the relative risk of hospitalization increased as the performance measure quintile increased from the reference group (combined Q1 and Q2). For quintile 3, RR=1.05 (95% CI: 1.05, 1.06; p<0.001), quintile 4, RR=1.07 (95% CI: 1.06, 1.08; p<0.001), and quintile 5, RR=1.10 (95% CI: 1.09, 1.10; p<0.001).

2b1.4. What is your interpretation of the results in terms of demonstrating validity? (i.*e., what do the results mean and what are the norms for the test conducted?*)

Results of the Poisson regression suggest the predictive relationship of higher catheter use with higher mortality and hospitalization, as measured by the respective standardized mortality and hospitalization rates, compared to facilities with a lower proportion of patients with a long-term catheter.

2019 Submission

Results of the Poisson regression suggest higher long-term catheter use is associated with higher risks of mortality and hospitalization (measured by the respective standardized mortality and hospitalization ratios), compared to facilities with lower long-term catheter rates.

2b2. EXCLUSIONS ANALYSIS

NA ☐ no exclusions — *skip to section 2b3*

2b2.1. Describe the method of testing exclusions and what it tests (*describe the steps—do not just name a method; what was tested, e.g., whether exclusions affect overall performance scores; what statistical analysis was used*)

The following exclusions are applied to the denominator:

Patients with a catheter that have limited life expectancy. Limited life expectancy is defined as:

- Patients under hospice care in the current reporting month
- Patients with metastatic cancer in the past 12 months
- Patients with end stage liver disease in the past 12 months
- Patients with coma or anoxic brain injury in the past 12 months

The facility-level mean percentage of patient-months with a catheter for at least three months with and without the patient-month exclusions are calculated and compared.

2019 Submission

The analyses described above were carried out for this submission, using 2018 data. Medicare inpatient and outpatient claims were used to determine the presence of the exclusion conditions.

2b2.2. What were the statistical results from testing exclusions? (*include overall number and percentage of individuals excluded, frequency distribution of exclusions across measured entities, and impact on performance measure scores*)

The following tables show percent of patient-months at risk and number of unique patients excluded as a result of the above mentioned exclusion strategy.

Table 1: Percent of patient-months at risk excluded

Year	Before Exclusion	After Exclusion	Percent
2014	4,314,450	4,274,619	0.92%

Table 2: Number and percent of unique patients excluded

Year	Before Exclusion	After Exclusion	Percent
2014	468,910	457,902	2.35%

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

Catheter Rate	N	Mean	Standard Deviation	Minimum	Maximum
Before exclusion	5928	0.121	0.068	0.000	0.597
After exclusion	5928	0.118	0.066	0.000	0.582

Figure 1: Scatterplot – Facility Catheter Rate with and without Exclusions

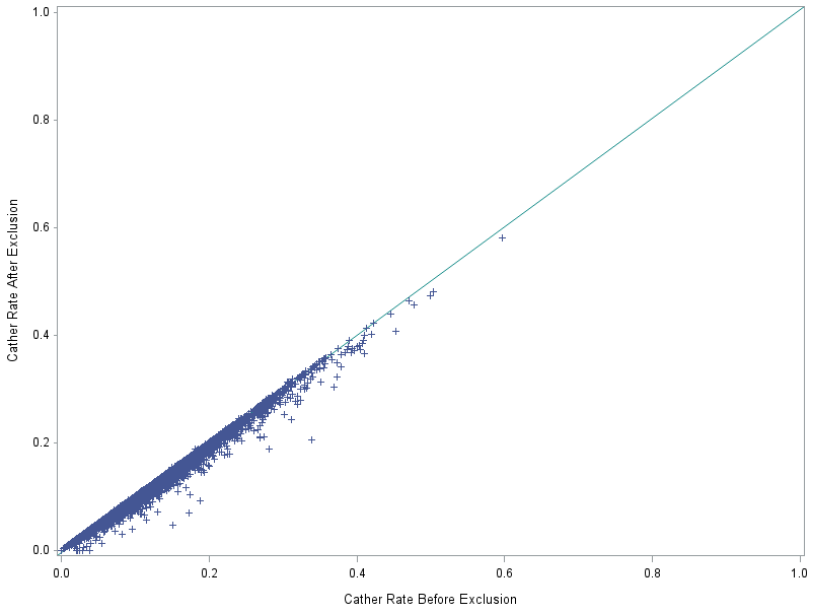
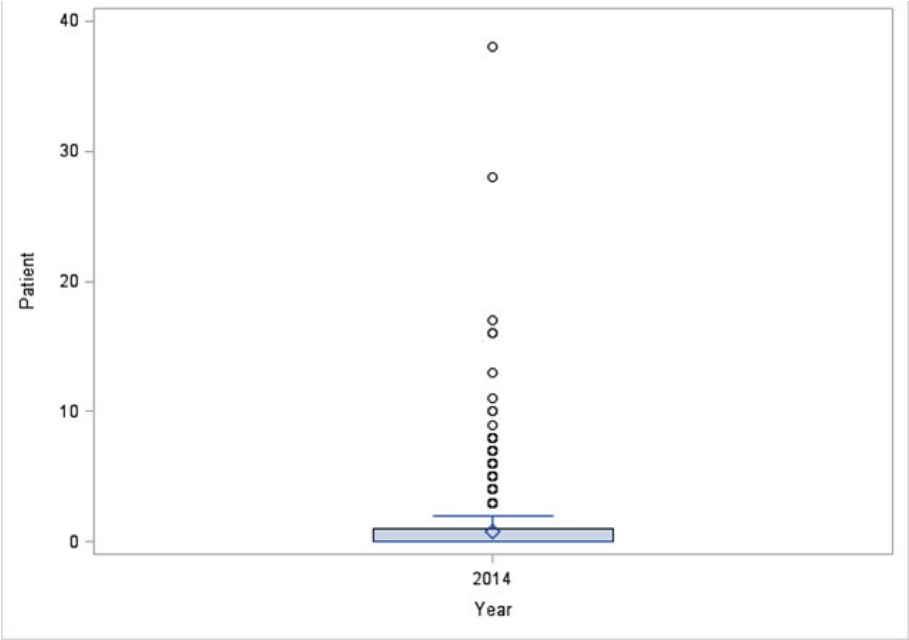


Figure 2. Distribution of Excluded Patients at the facility level for 2014



2019 Submission

The following tables show the percent of patient-months at risk and the number of unique patients excluded as a result of the exclusion strategy.

Table 1: Percent of patient-months at risk excluded, 2018 data

Year	Before Exclusion	After Exclusion	Percent
2018	5,130,974	5,068,460	1.22%

Table 2: Number and percent of unique patients excluded, 2018 data

Year	Before Exclusion	After Exclusion	Percent
2018	544,938	539,550	0.99%

Table 3: Distribution of performance scores before and after the exclusion, 2018 data

Catheter Rate	N	Mean	Standard Deviation	Minimum	Maximum
Before exclusion	6838	0.131	0.075	0	0.892
After exclusion	6838	0.124	0.073	0	0.899

Figure 1: Scatterplot – Facility Catheter Rate with and without Exclusions, 2018 data

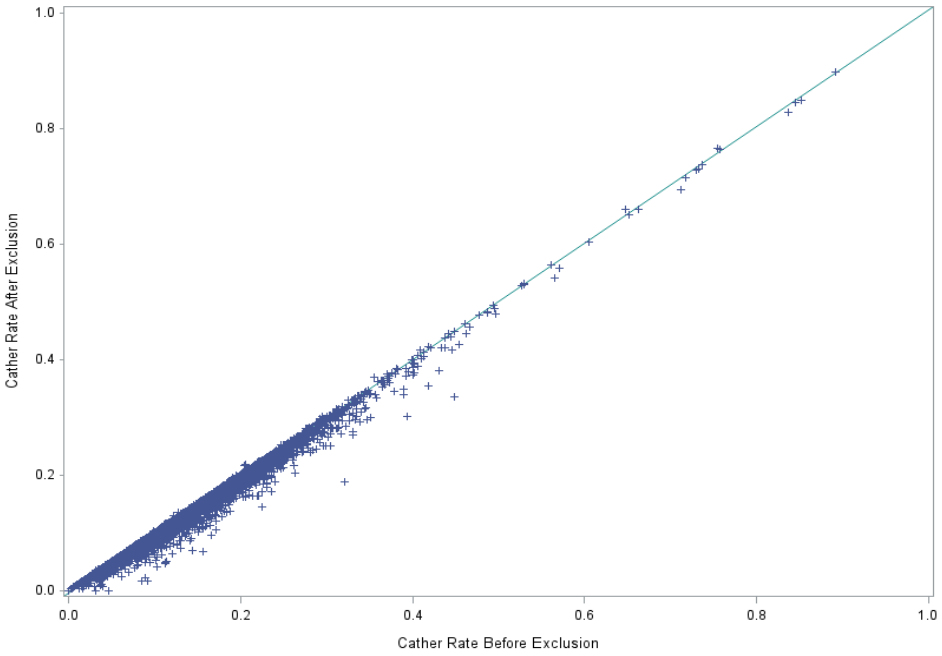
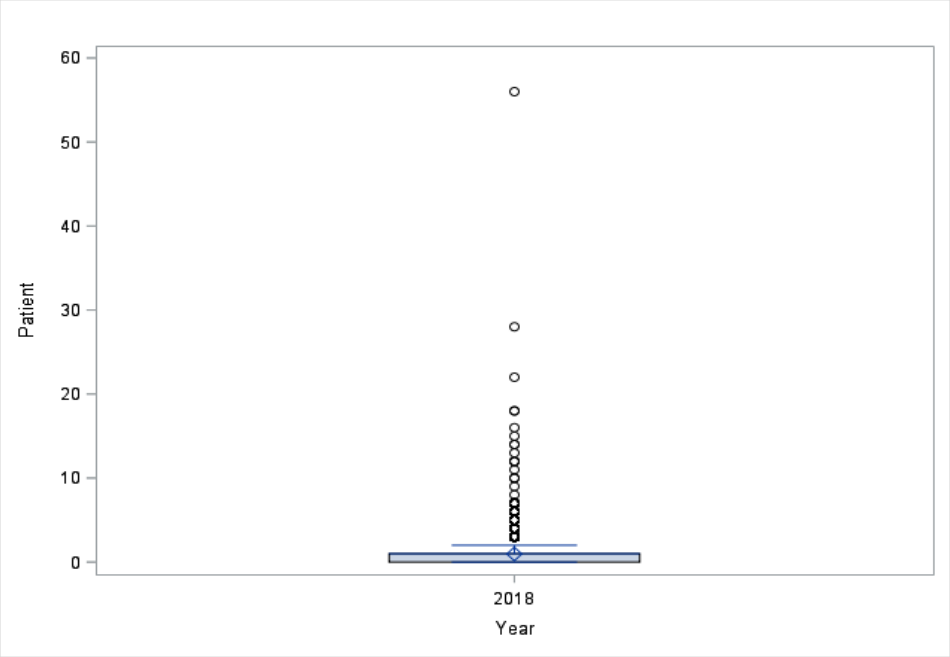


Figure 2. Distribution of Excluded Patients at the facility level for 2018



2b2.3. What is your interpretation of the results in terms of demonstrating that exclusions are needed to prevent unfair distortion of performance results? (*i.e., the value outweighs the burden of increased data collection and analysis. Note: **If patient preference is an exclusion**, the measure must be specified so that the effect on the performance score is transparent, e.g., scores with and without exclusion*)

The exclusion criteria are necessary since the percentage of patients excluded at each facility is not evenly distributed across facilities (Distribution shown in the boxplot). Due to the unequal distribution across facilities, the exclusion criteria take into account that some facilities treat a higher portion of patients with limited life expectancy. Additionally, our results shown in both the scatter-plot (Figure 1) as well as the Pearson Correlation Coefficient of 0.993 (p-value <0.0001) between the mean percentage of patient months with a long-term catheter with and without the exclusion suggests that the overall impact of the exclusion on the measure's validity is not substantial since the two are highly correlated.

2019 Submission

Using 2018 data, we show the exclusion criteria are necessary since the percentage of patients excluded at each facility is not evenly distributed across facilities (distribution shown in the boxplot above, figure 2). Due to the unequal distribution across facilities, the exclusion criteria take into account that some facilities treat a higher proportion of patients with limited life expectancy. Additionally, our results shown in both the scatter-plot (Figure 1) as well as the Pearson Correlation Coefficient of 0.993 (p-value <0.0001) between long-term catheter rates with and without the exclusion suggest that the overall impact of the exclusion on the measure's validity is not substantial since the two are highly correlated.

2b3. RISK ADJUSTMENT/STRATIFICATION FOR OUTCOME OR RESOURCE USE MEASURES

If not an intermediate or health outcome, or PRO-PM, or resource use measure, skip to section 2b4.

2b3.1. What method of controlling for differences in case mix is used?

☒ **No risk adjustment or stratification**

☐ **Statistical risk model with** Click here to enter number of factors **risk factors**

☐ **Stratification by** Click here to enter number of categories **risk categories**

☐ **Other,** Click here to enter description

2b3.1.1 If using a statistical risk model, provide detailed risk model specifications, including the risk model method, risk factors, coefficients, equations, codes with descriptors, and definitions.

N/A

2b3.2. If an outcome or resource use component measure is not risk adjusted or stratified, provide rationale and analyses to demonstrate that controlling for differences in patient characteristics (case mix) is not needed to achieve fair comparisons across measured entities.

Risk adjustment is not appropriate for this measure because of the primary goal of disincentivizing catheter use for incident and particularly prevalent dialysis patients. This measure was reviewed by the 2015 vascular access TEP which also did not recommend risk adjustment.

The TEP felt that minimizing catheter use is paramount and that while catheters may potentially be acceptable for some patients, they addressed this through identifying patient level exclusion criteria rather than risk adjustment, so as not to penalize providers that treat patients that have limited life expectancy or limit those patients' access to care.

Consistent with the TEP's concerns, potential risk adjustors in a catheter measure would apply to a large portion of both incident and prevalent ESRD patients, and therefore may not function as a disincentive to reduce catheter use, which is the intent of the measure. Applying the exclusions more appropriately accounts for conditions in a very specific subset of patients where a catheter may be the only or an acceptable access type. Additionally, the fistula measure (intended to be reported with the catheter measure) includes risk adjustment based on the TEP's recommendation that facility success in fistula use (versus graft or catheter) will be limited in patients with certain comorbidities and other patient characteristics.

2019 Submission

The rationale provided above still applies for this submission.

2b3.3a. Describe the conceptual/clinical and statistical methods and criteria used to select patient factors (clinical factors or social risk factors) used in the statistical risk model or for stratification by risk (*e.g., potential factors identified in the literature and/or expert panel; regression analysis; statistical significance of p<0.10; correlation of x or higher; patient factors should be present at the start of care*) **Also discuss any "ordering" of risk factor inclusion**; for example, are social risk factors added after all clinical factors?

2b3.3b. How was the conceptual model of how social risk impacts this outcome developed? Please check all that apply:

☐ **Published literature**

☐ **Internal data analysis**

☐ **Other (please describe)**

2b3.4a. What were the statistical results of the analyses used to select risk factors?

N/A

2b3.4b. Describe the analyses and interpretation resulting in the decision to select social risk factors *(e.g. prevalence of the factor across measured entities, empirical association with the outcome, contribution of unique variation in the outcome, assessment of between-unit effects and within-unit effects.)* **Also describe the impact of adjusting for social risk (or not) on providers at high or low extremes of risk.**

N/A

2b3.5. Describe the method of testing/analysis used to develop and validate the adequacy of the statistical model or stratification approach (*describe the steps—do not just name a method; what statistical analysis was used*)

Provide the statistical results from testing the approach to controlling for differences in patient characteristics (case mix) below.

If stratified, skip to 2b3.9

N/A

2b3.6. Statistical Risk Model Discrimination Statistics (*e.g., c-statistic, R-squared*)**:**
N/A

2b3.7. Statistical Risk Model Calibration Statistics (*e.g., Hosmer-Lemeshow statistic*):
N/A

2b3.8. Statistical Risk Model Calibration – Risk decile plots or calibration curves:
N/A

2b3.9. Results of Risk Stratification Analysis:

N/A

2b3.10. What is your interpretation of the results in terms of demonstrating adequacy of controlling for differences in patient characteristics (case mix)? (i.*e., what do the results mean and what are the norms for the test conducted*)
N/A

2b3.11. Optional Additional Testing for Risk Adjustment (*not required, but would provide additional support of adequacy of risk model, e.g., testing of risk model in another data set; sensitivity analysis for missing data; other methods that were assessed*)

N/A

2b4. IDENTIFICATION OF STATISTICALLY SIGNIFICANT & MEANINGFUL DIFFERENCES IN PERFORMANCE

2b4.1. Describe the method for determining if statistically significant and clinically/practically meaningful differences in performance measure scores among the measured entities can be identified (*describe the steps—do not just name a method; what statistical analysis was used? Do not just repeat the information provided related to performance gap in 1b)*

Differences in measure performance were evaluated separately for each facility using patient level analyses. For each facility, the proportion of patient-months with catheter ≥ three months, calculated at the year-level, was compared to the overall national distribution.

Note that the monthly based measure is a simple average of binary outcomes across individuals in the facility, for which the binary outcome equals 0 if no catheter is present, and equals 1 if a catheter ≥ three months is present. The differences in proportions can be compared using Fisher's Exact tests or its normal approximation. The yearly based measure, however, is not a simple average of binary outcomes and we instead used a re-sampling based exact test, with re-sampling generated from the population distribution of the patient level outcomes. Due to the non-symmetric structure of the measure distributions, a one-sided test with significance level 0.025 is used (corresponding to a cutoff=0.05 in a two-sided test). To calculate the p-value, we assess the probability that patients in each facility would experience a number of events (i.e., months dialyzing with catheter ≥ three months) more extreme than what was actually observed if the null

hypothesis were true, where the null hypothesis is that a patient in each facility will follow the overall national distribution.

2019 Submission

The methodology described above was applied to the calculation of meaningful differences, using 2018 data. For this submission, a two-sided test with significance level of 0.05 is used.

2b4.2. What were the statistical results from testing the ability to identify statistically significant and/or clinically/practically meaningful differences in performance measure scores across measured entities? (e.g., *number and percentage of entities with scores that were statistically significantly different from mean or some benchmark, different from expected; how was meaningful difference defined*)

Table 4. Proportion of facilities with statistically significant differences (p-value < 0.025)

Category	Number of facilities	Percent of facilities
As expected	5,211	87.9%
Worse than expected	717	12.1%

2019 Submission

Table 4. Proportion of facilities with statistically significant differences (p-value < 0.025)

Category	Number of facilities	Percent of facilities
Better than expected	914	13.4%
As expected	5181	75.8%
Worse than expected	743	10.9%

2b4.3. What is your interpretation of the results in terms of demonstrating the ability to identify statistically significant and/or clinically/practically meaningful differences in performance across measured entities?

(i*.e., what do the results mean in terms of statistical and meaningful differences?*)
For the annual percentage of patients with a long-term catheter as the performance measure, 5,211 (87.9%) facilities have achieved expected performance, and 717 (12%) facilities have performed worse than expected (higher catheter rate).

In general, lower rates of catheter use for three months or more represent better quality of care. This analysis demonstrates both practical and statistically significant differences in performance across facilities based on their proportion of patient months with a catheter for three months or greater.

2019 Submission

For the annual percentage of patients with a long-term catheter as the performance measure, 6,095 (89.1%) facilities have achieved either as expected or better than expected performance, and 743 (10.9%) facilities have performed worse than expected (higher catheter rate).

In general, lower rates of long-term catheter use for three months or more represent better quality of care. This analysis demonstrates both practical and statistically significant differences in performance across facilities based on their proportion of patient months with a catheter for three months or greater.

2b5. COMPARABILITY OF PERFORMANCE SCORES WHEN MORE THAN ONE SET OF SPECIFICATIONS

If only one set of specifications, this section can be skipped.

Note*: This item is directed to measures that are risk-adjusted (with or without social risk factors)* ***OR*** *to measures with more than one set of specifications/instructions (e.g., one set of specifications for how to identify and compute the measure from medical record abstraction and a different set of specifications for claims or eMeasures). It does not apply to measures that use more than one source of data in one set of specifications/instructions (e.g., claims data to identify the denominator and medical record abstraction for the numerator).* ***Comparability is not required when comparing performance scores with and without social risk factors in the risk adjustment model. However, if comparability is not demonstrated for measures with more than one set of specifications/instructions, the different specifications (e.g., for medical records vs. claims) should be submitted as separate measures.***

2b5.1. Describe the method of testing conducted to compare performance scores for the same entities across the different data sources/specifications (*describe the steps—do not just name a method; what statistical analysis was used*)

N/A

2b5.2. What were the statistical results from testing comparability of performance scores for the same entities when using different data sources/specifications? (*e.g., correlation, rank order*)
N/A

2b5.3. What is your interpretation of the results in terms of the differences in performance measure scores for the same entities across the different data sources/specifications? (i*.e., what do the results mean and what are the norms for the test conducted*)
N/A

2b6. MISSING DATA ANALYSIS AND MINIMIZING BIAS

2b6.1. Describe the method of testing conducted to identify the extent and distribution of missing data (or nonresponse) and demonstrate that performance results are not biased due to systematic missing data (or

differences between responders and nonresponders) and how the specified handling of missing data minimizes bias (*describe the steps—do not just name a method; what statistical analysis was used*)

The LTC measure is applied to all patients regardless of Medicare coverage. The LTC measure is based on data from CROWNWeb (representative of all ESRD dialysis patients) and Medicare claims. The source of vascular access type is CROWNWeb. Missing data for vascular access type occurs rarely. We report the frequency of the overall percentage of patient months with missing vascular access type

Additionally, ascertainment of comorbidities for applying the comorbidity exclusions is determined by the presence of the conditions on Medicare claims in the prior 12 months. We assessed the percentage of patient months where we are unable to identify presence of comorbidities for the limited life expectancy exclusions.

2b6.2. What is the overall frequency of missing data, the distribution of missing data across providers, and the results from testing related to missing data? (*e.g., results of sensitivity analysis of the effect of various rules for missing data/nonresponse; if no empirical sensitivity analysis, identify the approaches for handling missing data that were considered and pros and cons of each*)

Table 5. Frequency of the overall percentage of patient months with missing vascular access type

Catheter	N	%
Missing	109747	2.16
No	4125977	81.21
Yes	845188	16.63

We were unable to determine the presence of comorbidities for the limited life expectancy exclusion conditions in 21.4% of patient months.

2b6.3. What is your interpretation of the results in terms of demonstrating that performance results are not biased due to systematic missing data (or differences between responders and nonresponders) and how the specified handling of missing data minimizes bias**?** (i.*e., what do the results mean in terms of supporting the selected approach for missing data and what are the norms for the test conducted; if no empirical analysis, provide rationale for the selected approach for missing data*)

Failure to report vascular access type indicates facilities are not appropriately monitoring or reporting vascular access outcomes as required. Reporting months with missing values are not excluded from this measure. We count patient months with missing vascular access type in both the denominator and the numerator for LTC. Missing months are used as a component of the measure numerator where missing is treated as a "catheter." Since these patient months are not excluded from the measure, bias from missing vascular access type is not a consideration for LTC.

The percentage of patient months that we are unable to determine presence of the comorbidity exclusions is 21.4% and we acknowledge this is a general limitation of relying on FFS Medicare claims for ascertaining comorbidities. However, as shown in the exclusion analysis, LTC with and without the exclusions applied are highly correlated. This suggests the unavailability of claims for non-Medicare patients to identify exclusions does not bias LTC performance scores.

3. Feasibility

Extent to which the specifications including measure logic, require data that are readily available or could be captured without undue burden and can be implemented for performance measurement.

3a. Byproduct of Care Processes

For clinical measures, the required data elements are routinely generated and used during care delivery (e.g., blood pressure, lab test, diagnosis, medication order).

3a.1. Data Elements Generated as Byproduct of Care Processes.

Generated or collected by and used by healthcare personnel during the provision of care (e.g., blood pressure, lab value, diagnosis, depression score), Coded by someone other than person obtaining original information (e.g., DRG, ICD-9 codes on claims)

If other:

3b. Electronic Sources

The required data elements are available in electronic health records or other electronic sources. If the required data are not in electronic health records or existing electronic sources, a credible, near-term path to electronic collection is specified.

3b.1. To what extent are the specified data elements available electronically in defined fields (*i.e., data elements that are needed to compute the performance measure score are in defined, computer-readable fields*) Update this field for **maintenance of endorsement**.

ALL data elements are in defined fields in a combination of electronic sources

3b.2. If ALL the data elements needed to compute the performance measure score are not from electronic sources, specify a credible, near-term path to electronic capture, OR provide a rationale for using other than electronic sources. For **maintenance of endorsement**, if this measure is not an eMeasure (eCQM), please describe any efforts to develop an eMeasure (eCQM).

N/A

3b.3. If this is an eMeasure, provide a summary of the feasibility assessment in an attached file or make available at a measure-specific URL. Please also complete and attach the NQF Feasibility Score Card.

Attachment:

3c. Data Collection Strategy

Demonstration that the data collection strategy (e.g., source, timing, frequency, sampling, patient confidentiality, costs associated with fees/licensing of proprietary measures) can be implemented (e.g., already in operational use, or testing demonstrates that it is ready to put into operational use). For eMeasures, a feasibility assessment addresses the data elements and measure logic and demonstrates the eMeasure can be implemented or feasibility concerns can be adequately addressed.

3c.1. Required for maintenance of endorsement. Describe difficulties (as a result of testing and/or operational use of the measure) regarding data collection, availability of data, missing data, timing and frequency of data collection, sampling, patient confidentiality, time and cost of data collection, other feasibility/implementation issues.

IF instrument-based, consider implications for both individuals providing data (patients, service recipients, respondents) and those whose performance is being measured.

Data collection is accomplished via Medicare Claims and CROWNWeb, a web-based and electronic batch submission platform maintained and operated by CMS contractors. Measures reported on DFC are reviewed on a regular basis by dialysis facility providers. Review of comments and questions received in the past for the long term catheter rate showed very few instances of concern expressed about inaccurate or missing data.

3c.2. Describe any fees, licensing, or other requirements to use any aspect of the measure as specified *(e.g., value/code set, risk model, programming code, algorithm)*.

N/A

4. Usability and Use

Extent to which potential audiences (e.g., consumers, purchasers, providers, policy makers) are using or could use performance results for both accountability and performance improvement to achieve the goal of high-quality, efficient healthcare for individuals or populations.

4a. Accountability and Transparency

Performance results are used in at least one accountability application within three years after initial endorsement and are publicly reported within six years after initial endorsement (or the data on performance results are available). If not in use at the time of initial endorsement, then a credible plan for implementation within the specified timeframes is provided.

4.1. Current and Planned Use

NQF-endorsed measures are expected to be used in at least one accountability application within 3 years and publicly reported within 6 years of initial endorsement in addition to performance improvement.

Specific Plan for Use	Current Use (for current use provide URL)
	Public Reporting Dialysis Facility Compare https://www.medicare.gov/dialysisfacilitycompare/ Payment Program https://www.qualitynet.org/esrd/esrdqip/measures ESRD QIP

4a1.1 For each CURRENT use, checked above (update for maintenance of endorsement), provide:

- Name of program and sponsor
- Purpose
- Geographic area and number and percentage of accountable entities and patients included
- Level of measurement and setting

DFC:
Purpose: Dialysis Facility Compare helps patients find detailed information about Medicare-certified dialysis facilities. They can compare the services and the quality of care that facilities provide.
Geographic area: United States
Number of accountable entities: All Medicare-certified dialysis facilities that are eligible for the measure, and have at least 11 patients in the reporting month. For the most recent update to Dialysis Facility Compare (January 2020), 6916 facilities had a score reported.
Patients included: All patients who meet the requirements to be included in the measure from included facilities.
QIP:
Purpose: The ESRD QIP will reduce payments to ESRD facilities that do not meet or exceed certain performance standards. The measure was added to the program for PY2021
Geographic area: United States
Number of accountable entities: All Medicare-certified dialysis facilities that are eligible for the measure, and have at least 11 patients in the reporting month. The measure will first appear in the ESRD QIP for PY 2021 (released July 2020)

Patients included: All patients who meet the requirements to be included in the measure from included facilities.

4a1.2. If not currently publicly reported OR used in at least one other accountability application (e.g., payment program, certification, licensing) what are the reasons? (*e.g., Do policies or actions of the developer/steward or accountable entities restrict access to performance results or impede implementation?*)

N/A

4a1.3. If not currently publicly reported OR used in at least one other accountability application, provide a credible plan for implementation within the expected timeframes -- any accountability application within 3 years and publicly reported within 6 years of initial endorsement. (*Credible plan includes the specific program, purpose, intended audience, and timeline for implementing the measure within the specified timeframes. A plan for accountability applications addresses mechanisms for data aggregation and reporting.*)

N/A

4a2.1.1. Describe how performance results, data, and assistance with interpretation have been provided to those being measured or other users during development or implementation.

How many and which types of measured entities and/or others were included? If only a sample of measured entities were included, describe the full population and how the sample was selected.

Results of this measure are currently reported on Dialysis Facility Compare, and are slated for reporting in the ESRD Quality Incentive Program for PY 2021. All Medicare-certified dialysis facilities are eligible for reporting in both programs (approximately 7,000 dialysis facilities). Each program has a helpdesk and supporting documentation available to assist with interpretation of the measure results.

The measure developer (UM-KECC) produces and distributes the DFC data under contract with CMS. Other CMS contractors calculate and distribute the ESRD QIP measure results.

4a2.1.2. Describe the process(es) involved, including when/how often results were provided, what data were provided, what educational/explanatory efforts were made, etc.

For DFC, the results are first reported to facilities via a closed preview period, where facilities can review their data prior to each of the quarterly updates of the public facing Dialysis Facility Compare website. These preview reports are posted on dialysisdata.org, where facilities can also find a detailed Guide to the Quarterly Dialysis Facility Compare Reports and other supporting documentation. Facilities can submit comments/questions about their results at any time, and can request patient lists for their facilities during the specified preview periods.

For the ESRD QIP, results are first reported to facilities via closed preview period on an annual basis; facilities can review their data prior to the results becoming public at the end of the calendar year. These preview reports are posted on qualitynet.org, where facilities can also find supporting documentation and can submit comments/questions about their results.

A measures manual that describes the calculations for both of these programs in detail is published on the CMS website: https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/ESRDQIP/06_MeasuringQuality.html

4a2.2.1. Summarize the feedback on measure performance and implementation from the measured entities and others described in 4d.1.

Describe how feedback was obtained.

For DFC, feedback can be provided any time through contacting the dialysisdata.org helpdesk. Preview periods allow for specific times for facilities review and comment on measure calculations, and provide an opportunity to request a patient list.

For the ESRD QIP, feedback can be provided any time through contacting the QIP helpdesk. Preview periods allow for specific times for facilities review and comment on measure calculations. Comments can also be submitted in response to the Notice of Proposed Rulemaking for each QIP payment year.

4a2.2.2. Summarize the feedback obtained from those being measured.

DFC: Comments received during DFC preview periods tend to be technical nature, asking for clarification about how the LTC is calculated for particular facilities, including questions about patient assignment, how the limited life expectancy exclusions are determined, and requests for confirmation of patient vascular access type in a specific month. UM-KECC investigates all inquiries received about specific patients and works with facilities to ensure that they understand their measure results and that data discrepancies are resolved.

QIP: The LTC measure has not yet been reported in the program.

4a2.2.3. Summarize the feedback obtained from other users

QIP: Since the LTC was first proposed in the PY 2021 proposed rule, several commenters requested that this measure account for situations for which the patient has elected not to have a fistula (patient choice/preference). CMS also received comments about facilities possibly being doubly penalized if they have low fistula rates, and high catheter rates, and also do not get credit for grafts. Comments were also received about adding clinical risk adjustment to LTC, and for additional exclusions.

4a2.3. Describe how the feedback described in 4a2.2.1 has been considered when developing or revising the measure specifications or implementation, including whether the measure was modified and why or why not.

We evaluated the suggested changes made by users of the LTC however we did not make changes in response to this feedback. In response to feedback that the measure should account for patient choice in selecting a vascular access, we acknowledge that it is important that patient preference is taken into account in treatment plans and a patient's "ESKD life plan", as referenced in the updated 2019 KDOQI vascular access guidelines. Patient choice or preference is ostensibly a patient reported outcome however at this time there are no standard criteria for how to validate informed choice, such as a patient's preference to have a catheter (or arteriovenous graft) versus an AV fistula. Check-boxes indicating "received educational materials" or attested to selecting their preferred access type may not be sufficient for determining whether an informed and express choice was made by the patient. Doing so would require ascertaining and measuring 1) what constitutes adequate vascular access education by a nephrologist from the patient's perspective and 2) how that in turn resulted in an informed choice. Accurately capturing informed patient choice may be a particular concern for vulnerable patients.

In response to concerns about facilities potentially being doubly penalized by the fistula and catheter vascular access measures, we explain that when used together, AV fistula is considered a positive outcome and prolonged use of a tunneled catheter as a negative outcome, while graft use is neutral and does not count against a facility. With the growing recognition that some patients have exhausted options for an arteriovenous fistula, or have comorbidities that may limit the success of AV fistula creation, pairing the measures accounts for all three vascular access options. This paired incentive structure that relies on both measures reflects consensus best practice, and supports maintenance of the gains in vascular access success achieved via the Fistula First/Catheter Last Project and the ESRD Networks over the last decade. Additionally, the long term catheter rate measure applies exclusions for certain conditions recognizing that catheter placement may be the only means of vascular access for these patient sub-populations. Specifically, LTC (and SFR) excludes patients with a catheter that have limited life expectancy, defined as being under hospice care in the current reporting month, or a diagnosis with metastatic cancer, end stage liver disease, coma or anoxic brain injury in the past 12 months.

In response to comments about expanding the exclusion criteria, many of the comorbidity based exclusions suggested by commenters are either associated with shortened life expectancy or low likelihood of successful fistula placement. As described above, specific conditions associated with limited life expectancy are already part of the exclusion criteria for LTC (and SFR). Multiple prior failed vascular access attempts were considered by the TEP as an exclusion criterion to address the exhaustion of vascular sites or failed attempts to create a fistula or graft, however consensus was not reached by the TEP on how best to implement this exclusion. At the present time, historical vascular access data in CROWNWeb do not have enough reliability to be used as

part of an exclusion criteria. This will be re-evaluated with future updates as part of the measure maintenance process. Finally, some comments suggested risk adjusting LTC for certain severe clinical conditions. As described above, LTC applies several exclusions for limited life expectancy, while the standardized fistula rate measure also includes risk adjustment for patient clinical factors where fistula placement may be either more difficult or not appropriate and acknowledges that in certain circumstances an AV graft may be the best access option.

Improvement

Progress toward achieving the goal of high-quality, efficient healthcare for individuals or populations is demonstrated. If not in use for performance improvement at the time of initial endorsement, then a credible rationale describes how the performance results could be used to further the goal of high-quality, efficient healthcare for individuals or populations.

4b1. Refer to data provided in 1b but do not repeat here. Discuss any progress on improvement (trends in performance results, number and percentage of people receiving high-quality healthcare; Geographic area and number and percentage of accountable entities and patients included.)

If no improvement was demonstrated, what are the reasons? If not in use for performance improvement at the time of initial endorsement, provide a credible rationale that describes how the performance results could be used to further the goal of high-quality, efficient healthcare for individuals or populations.

Q1 2018: N of facilities = 6711, Mean % = 12.73, Std Dev % = 9.64, Min % = 0, Max % = 100

Q2 2018: N of facilities = 6779, Mean % = 12.63, Std Dev % = 8.75, Min % = 0, Max % = 100

Q3 2018: N of facilities = 6816, Mean % = 12.44, Std Dev % = 8.37, Min % = 0, Max % = 100

Q4 2018: N of facilities = 6828, Mean % = 12.36, Std Dev % = 8.11, Min % = 0, Max % = 100

The percentage of facility level rates of long-term catheter use declined across each quarter of 2018, indicting improvement in the reduction of long-term catheter use over the period.

4b2. Unintended Consequences

The benefits of the performance measure in facilitating progress toward achieving high-quality, efficient healthcare for individuals or populations outweigh evidence of unintended negative consequences to individuals or populations (if such evidence exists).

4b2.1. Please explain any unexpected findings (positive or negative) during implementation of this measure including unintended impacts on patients.

None

4b2.2. Please explain any unexpected benefits from implementation of this measure.

None

5. Comparison to Related or Competing Measures

If a measure meets the above criteria and there are endorsed or new related measures (either the same measure focus or the same target population) or competing measures (both the same measure focus and the same target population), the measures are compared to address harmonization and/or selection of the best measure.

5. Relation to Other NQF-endorsed Measures

Are there related measures (conceptually, either same measure focus or target population) or competing measures (conceptually both the same measure focus and same target population)? If yes, list the NQF # and title of all related and/or competing measures.

Yes

5.1a. List of related or competing measures (selected from NQF-endorsed measures)

2594 : Optimal End Stage Renal Disease (ESRD) Starts

5.1b. If related or competing measures are not NQF endorsed please indicate measure title and steward.

5a. Harmonization of Related Measures

The measure specifications are harmonized with related measures;

OR

The differences in specifications are justified

5a.1. If this measure conceptually addresses EITHER the same measure focus OR the same target population as NQF-endorsed measure(s):

Are the measure specifications harmonized to the extent possible?

No

5a.2. If the measure specifications are not completely harmonized, identify the differences, rationale, and impact on interpretability and data collection burden.

Measure 2594 is not a dialysis facility level measure. The setting focus addresses a different provider type which falls outside the purview of measures evaluating dialysis facility performance on fistula use. This suggests a fundamental difference in the measure target populations, setting and intent that cannot be harmonized. Additionally, the measure is limited to incident patients, while the LTC measure includes both incident and prevalent patients as the measured population.

5b. Competing Measures

The measure is superior to competing measures (e.g., is a more valid or efficient way to measure);

OR

Multiple measures are justified.

5b.1. If this measure conceptually addresses both the same measure focus and the same target population as NQF-endorsed measure(s):

Describe why this measure is superior to competing measures (e.g., a more valid or efficient way to measure quality); OR provide a rationale for the additive value of endorsing an additional measure. (Provide analyses when possible.)

There are no competing measures.

Appendix

A.1 Supplemental materials may be provided in an appendix. All supplemental materials (such as data collection instrument or methodology reports) should be organized in one file with a table of contents or bookmarks. If material pertains to a specific submission form number, that should be indicated. Requested information should be provided in the submission form and required attachments. There is no guarantee that supplemental materials will be reviewed.

Attachment **Attachment:** 2978__Flow_Chart_.pdf

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Co.3 Measure Developer if different from Measure Steward: University of Michigan Kidney Epidemiology and Cost Center

Co.4 Point of Contact: Jennifer, Sardone, jmsto@med.umich.edu, 734-548-3057-

Additional Information

Ad.1 Workgroup/Expert Panel involved in measure development

Provide a list of sponsoring organizations and workgroup/panel members' names and organizations. Describe the members' role in measure development.

According to the CMS Measure Management System Blueprint, TEPs are advisory to the measure contractor. In this advisory role, the primary duty of the TEP is to suggest candidate measures and related specifications, review any existing measures, and determine if there is sufficient evidence to support the proposed candidate measures.

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Measure Developer/Steward Updates and Ongoing Maintenance

Ad.2 Year the measure was first released: 2016

Ad.3 Month and Year of most recent revision: 04, 2016

Ad.4 What is your frequency for review/update of this measure? Annually

Ad.5 When is the next scheduled review/update for this measure? 04, 2017

Ad.6 Copyright statement:

Ad.7 Disclaimers:

Ad.8 Additional Information/Comments: