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

Purple text represents the responses from measure developers.
Red text denotes developer information that has changed since the last measure evaluation review.

Brief Measure Information

NQF #: 3567

Corresponding Measures:

De.2. Measure Title: Hemodialysis Vascular Access: Practitioner Level 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 attributable to an individual practitioner or group practice.

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

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 under the care of the same practitioner or group partner.

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 for any portion of the reporting month
- Patient-months where there are more than one MCP provider listed for the month.

In addition, patients with a catheter that have limited life expectancy, as defined by the following criteria are excluded:

- 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

This measure does not exclude patients who have exhausted their vascular access options. A 2015 Technical Expert Panel had robust discussion about trying to add this to a facility-level catheter measure, but was unable to reach consensus about how best to incorporate such an exclusion criteria.

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

S.17. Data Source: Claims, Registry Data

S.20. Level of Analysis: Clinician : Group/Practice, Clinician : Individual

IF Endorsement Maintenance – Original Endorsement Date: Most Recent Endorsement Date: N/A

Preliminary Analysis: New Measure

Criteria 1: Importance to Measure and Report

1a. Evidence

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**

Evidence Summary

- This is a claims and registry data based intermediate outcome measure at the clinician: individual and group/practice level assessing the percentage of adult hemodialysis patient-months using a catheter continuously for three months or longer for vascular access attributable to an individual practitioner or group practice.
- The developers provided a logic model demonstrating that 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 developer provided evidence to support this measures based on the 2006 National Kidney Foundations (NKF) Kidney Disease Outcomes Quality Initiative (KDOQI) Clinical Practice Guidelines and Clinical Practice Recommendations: Hemodialysis Adequacy, Peritoneal Dialysis Adequacy and 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 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)." Based on the KDOQI guidelines and the literature review, the developer summarized:
    - In general, the recent articles offered additional support for the general concepts laid out in the KDOQI guidelines that AV fistula continues 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.
    - Ultimately, physician-level 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.

Questions for the Committee:

- The evidence presented for this measure is very similar to that presented for the facility-level measure NQF 2978 Hemodialysis Vascular Access: Long-Term Catheter Rate, reviewed by the Committee in Spring 2020.
    - The Committee rated the evidence for NQF 2978 as moderate.
    - Is there any reason that similar evidence should differ?

Guidance from the Evidence Algorithm

Intermediate clinical outcome measure based on systematic review (Box 3) -> QQC presented (Box 4) -> Quantity: low/high; Quality: low/high; Consistency: moderate/high (Box 5) -> Moderate (Box 5b) -> Moderate

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.

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

Disparities

- Using data from January – December 2016, 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. The analysis results indicated potential disparity in prolonged use of a tunneled catheter among these groups:
    - Females are 33% more likely to have a long-term catheter than males;

- 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.
- Individuals 75 years of age and older were 13% more likely to have a long-term catheter and younger individuals 18-25 years of age were 43% more likely to have a long-term catheter when compared to patients 60-75 years of age.
- Those whose race is reported as "Other" were less likely to have a long-term catheter when compared to whites, as were Hispanics, when compared to non-Hispanics

- The developer also provided odds ratio of having a catheter for at least three months based on age, sex, race, ethnicity, employment status, medicare coverage and ADI (zipcode-level).

Questions for the Committee:

- Developer's analysis indicates that facility-level mean percentage physician-level mean percentage of patient-months with a long-term catheter was 9.7% (SD=9.0%). Is there a performance 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: For all measures (structure, process, outcome, patient-reported structure/process), empirical data are required. How does the evidence relate to the specific structure, process, or outcome being measured? Does it apply directly or is it tangential? How does the structure, process, or outcome relate to desired outcomes? For maintenance measures–are you aware of any new studies/information that changes the evidence base for this measure that has not been cited in the submission? For measures derived from a patient report: Measures derived from a patient report must demonstrate that the target population values the measured outcome, process, or structure.

- The structure is applied directly to describe the use of catheters vs. the use of fistulas and grafts in patients that are good candidates for a fistula first. Understanding that there are some circumstance that prevent fistulas first, the analyses demonstrated credible outcomes and data of patients' benefits and decreased mortality rate when a fistula is place instead of a long-term catheter. There is no knowledge of any missing resources that will alter the evidence.
- Guideline without most robust evidence bit some lower grade evidence and literature review generally supportive of concepts in measure; expert opinion supportive
- The evidence does apply directly to the negative effects of long term use of CVCs.
- Process Measure. Evidence rated as moderate. Intermediate clinical outcome measure based on systematic review.
- The data applies to the measure
- Good evidence
- intermediate outcome measure evidence strength low to moderate provider level
- Agree with moderate evidence to support decreasing use of long-term catheters
- Evidence unchanged, with no significant new evidence to change its rating. However, as noted, societal guidelines based mostly on expert opinion have emphasized a more individualized approach that pairs patient-driven priorities with life expectancy.
- Evidence confirms declining but still significant rate of catheter use.
- The evidence applies fairly directly and is related to the desired outcomes (less long term catheters). Not aware of new studies.
- Evidence is clear and supports the measure. agree with a moderate rating

- Preliminary Evidence Rating: Low, with potential for "Insufficient Evidence with Exception" with mitigation. Overall, the evidence presented is very similar to that presented for the facility-level LTCR measure (NQF 2978) reviewed by the Renal SC last spring, which the SC rated as "moderate." However, the updated KDOQI guidelines supporting the measure are based on "low" or "very low" quality evidence or "expert opinion"—which by the NQF Evidence Algorithm would give the measure a "low" rating. Moreover, in addition to limited life expectancy, the updated KDOQI Guideline 2.2 listed a number of circumstances where it may be clinically appropriate to use tunneled CVCs for short- or long-term durations, including when an AVF or AVG was created but is not ready for use; acute transplant rejection or other complications requiring dialysis; when a patient has a living donor transplant confirmed with an operation date in the near future (<90 days); patients with multiple prior failed AV accesses with no available options; and 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 risks and benefits. While patients with limited life expectancy are excluded, the measure does not appropriately account for the other numerous clinical scenarios laid out in the supporting KDOQI Guideline in which CVCs may be appropriate, which could result in unintended and adverse events in those patients for whom AV access in not suitable. The measure could be considered for NQF's "Insufficient Evidence with Exception" algorithm, but would need to be revised to account for scenarios beyond limited life expectancy where a LTC is an appropriate access choice to ensure that benefits outweigh potential harms. Specifically, two revisions would effectively address the majority of these cases and would strengthen the measure considerably: The addition of an exclusion for patients on ESRD treatment <90 days (which would also align the measure with numerous other CMS ESRD metrics), and establishing an "expected percentage" or threshold to allow for a certain anticipated number of patients with exhausted access options.
- KDOQI very low to moderate quality of evidence or expert opinion; additional studies included in the evidence
- Evidence applies directly and there is quality, quantity and consistency to measure
- The evidence is based on the updated KDOQI guidelines 2020. The evidence in the revised DOQI was graded as low or moderate but mostly through expert opinion. A literature review of 16 studies it was shown the infection rates were lower with an AVF or AVG. Evidence links CVC's to increased infection.

1b. Performance Gap: Was current performance data on the measure provided? How does it demonstrate a gap in care (variability or overall less than optimal performance) to warrant a national performance measure? Disparities: Was data on the measure by population subgroups provided? How does it demonstrate disparities in the care?

- Current performance data on measures was provided. This was highlighted through referenced data and literature reviews that demonstrated gaps in patient care and access to grafts and fistulas to include a national performance measure. Data by population subgroups were provided and addressed disparities such as, health insurance coverage, and patient's employment. Age and sex was also deemed as disparities.
- CROWNWeb data from 2016 with national range indicative of a gap; some disparities data provided as well
- There were disparities noted which will need to be explored in the future.
- Yes data was provided -indicated the physician-level mean percentage of patient-months with a long term catheter was 9.7% (SD=9.0%)
- There is limited current performance data.
- The performance gap has narrow quite substantially over the years. While still important 9.7 seems smaller than other higher priority items

- data do not necessarily suggest disparity in healthcare access her attitude, rather, they may reflect the effect of individual patient decision and choice.. (for example patients aged 18-25 may not wish to have a "disfiguring" AV access placed, especially if they are hoping to get a transplant. A 3 month(90 days) time interval is a very short interval for them to adapt to and accept these life changing events and to make a decision regarding their willingness to undergo access surgery and its attendant changes in their appearance and body image. in other populations (females)the presence of an AV catheter may reflect the inability to place a fistula or graft. The exclusion criteria do not take any of these into account which seems inappropriate for an intermediate outcome measure. The other subgroup analyses do not show Marked degrees of disparities of care for example insurance status, ethnicity, etc.
- Definitely shows a difference in women and younger patients. Might need to explore reasons for this variation. Could it be that practitioners are recommending AVF or AVG but patients are not consenting? Or don't have adequate vessels?
- There remain performance gaps; the measure does not appear topped out. Subgroup data was provided, noted some odds that are difficult to rationalize. with
- Significant variation between clinicians exists.
- Yes, performance data from 2016 was provided. The data show working aged people were more likely to have long term catheters (maybe waiting too long to get access surgery due to work situation?). Elders >75 also had higher likelihood of catheters possibly due to poor vascular structure due to age or choice of "no surgery" due to ailing health.
- Although improvement has been made, continued monitoring demonstrates continued improvement. Some disparity information was available. moderate rating seems appropriate.
- Preliminary Performance Gap Rating: Low to moderate. Because greater than 90% of clinicians/groups are already meeting the criteria for this measure, it is not clear that there is a sufficient performance gap to warrant the addition of a clinician-level national performance measures for which a facility-level metric is already in use. However, the measure may provide some opportunity for improved coordination between nephrologists and dialysis facilities and drive LTCRs further downward.
- Physician-level percentage of patient-months with LTC: 1st quartile 4.5%; median 8.3%; 3rd quartile 12.7%. Disparities examined, but the description of the findings does not fully align with the data presented and would be helpful to review and confirm the findings.
- Performance gap is indicated for select groups including age disparity. This disparity can be found not only from the facility level but by physician level as well.
- From 2006-2015 CVC rates decreased from 28% to 18% The physician mean was 9.7% with catheters in 2016 review. The practitioner level measure may have greater impact on AVF rates. 2016 data was reviewed for age, sex, race, ethnicity, and dialysis vintage using a regression analysis for long term catheter use. All of the determinants were statistically significant predicators of long term CVC use.

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: NQF Scientific Methods Panel Subgroup

Methods Panel Review (Combined)

Methods Panel Evaluation Summary:

This measure was reviewed by the Scientific Methods Panel. A summary of the measure and the Panel review is provided below.

Reliability

- Ratings for reliability: H-1; M-7; L-0; I-0 Pass; Measure passes with moderate rating.
- Reliability testing conducted at the score level:
    - Score level reliability testing conducted using inter-unit reliability (IUR) analysis as well as profile IUR (PIUR)
        - The IUR at practitioner level is 0.602. The PIUR at the practitioner level is 0.80.
        - The IUR at practitioner group level is 0.793. The PIUR at the practitioner group level is 0.815.

Validity

- Ratings for validity: H-1; M-5; L-1; I-1; Measure passes with moderate rating.
- Validity testing conducted at the score level:
    - Validity was assessed using the trend test to measure the association between practitioner level long-term catheter rates occurring in January-December 2016, and hospitalization and mortality in the following 12 months
    - Clinician: individual level
        - Mortality rates are 17.0, 18.4, and 20.8 (per 100 patient-years) for practitioners having long-term catheter rates falling into the lowest 10%, middle, and highest 10% categories respectively ($p<0.001$)

        - Percentages of patient hospitalization (all-cause) are 60.8%, 62.8% and 67.8% for practitioners having long-term catheter rates falling into the lowest 10%, middle, and highest 10% categories respectively (p<0.001)
    - Clinician: group/practice level
        - Mortality rates are 18.4, 18.3, and 21.3 (per 100 patient-years) for practitioner-groups having long-term catheter rates falling into the lowest 10%, middle, and highest 10% categories respectively (p<0.001)
        - Percentages of patient hospitalization (all cause) are 61.9%, 62.9% and 67.6% for practitioner-groups having long-term catheter rates falling into the lowest 10%, middle, and highest 10% categories respectively (p<0.001)

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: Which data elements, if any, are not clearly defined? Which codes with descriptors, if any, are not provided? Which steps, if any, in the logic or calculation algorithm or other specifications (e.g., risk/case-mix adjustment, survey/sampling instructions) are not clear? What concerns do you have about the likelihood that this measure can be consistently implemented?

- The data is clearly defined. There are no concerns about the consistent implementation of the measure.
- data elements seem clearly defined; consistent implementation seems likely
- The specifications are clear.
- Measure passes with moderate rating. No concerns.
- Definition of practitioner is not well defined. Most Nephrologists do not care for patients individually so it is not clear that practitioner-level data adds much. Patients are not excluded if AVG/AVF placement is not feasible.
- yes, no issues
- the provider IUR 0.6 is not robust PIUR which is aimed at identifying outliers is stronger
- no concerns
- No major concern
- All clearly defined
- Moderately reliable. I think that providers need to be engaged with the "life plan thinking" in order to improve their outcomes.

- Agree with the SMP findings
- Reliability of Measure Specifications: No concerns.
- Clarify the population included in the measure given the data sources; Clarify restrictions if<11 (inconsistency in the measure submission); IUR practitioner level 0.602, IUR at practitioner group level 0.793; PIUR higher compared to the IUR for the practitioner and practitioner group levels (0.804 and 0.815)
- No concerns that the measure can be implemented. Reliability testing is adequate.
- The measure is not risk adjusted. The data elements are extracted from CROWNWEB. I have a concern that if the data is missing the access is noted as a catheter. Non-Medicare patients are excluded. KDOQI recommended patient choice be considered which is not taken into account as an exclusion criteria. No concerns about the data being consistently implemented.

2a2. Reliability - Testing: Do you have any concerns about the reliability of the measure?

- No concerns
- reliability testing with IUR and PIUR OK for both practitioner and group levels
- The IUR provides a moderate reliability while the PIUR has a high reliability.
- No
- Reliability testing produced only moderate results
- No
- as above and data specifications are clearly defined
- no concerns
- No
- No
- I feel it is moderately reliable.
- Agree with SMP
- Preliminary Reliability Testing Rating: Moderate. IURs are acceptable for this measure. However, use of the PIUR to demonstrate reliability in metrics used in accountability programs intended to distinguish performance along a curve is inappropriate and should be discouraged.
- IUR acceptable, SMP generally rated as moderate; other considerations as previously outlined
- No concerns
- Both IUR and PIUR testing was used. Practitioner IUR was 0.602 PIUR was 0.084. The IUR at the group level was 0.793 and PIUR was 0.815. I have no concerns about the reliability

2b1. Validity -Testing: Do you have any concems with the testing results?

- There are no concerns with testing results.
- catheter rates compared to hospitalization and mortality data and for both practitioner and groups the associations in direction expected
- None
- No.
- At the group level, there is no difference between the best performing and the middle so it is not clear this measure successfully distinguishes any but the worst performing groups on mortality
- No issues, agree with the methods committee.

- KDOQI guidelines include a number of caveats and KDOQI considers it reasonable in valid clinical circumstances to use tunneled CVCs for short-term or long-term durations for incident patient. as proposed the measure does not include risk stratification and exclusion criteria are quite limited . there is NO adjustment for repetitive access failure, frailty life expectancy except as impacted for metastatic malignancy , hepatic failure hospice in prior reporting month. The impact of these concerns on patient access of choice (versus provider or group quality) has not been evaluated ,
- no concerns
- no
- No
- no concerns
- Agree with SMP
- Preliminary Validity Testing Rating: Moderate. The measure correlates in the expected directions with mortality and hospitalization rates.
- Need further clarification of the approach used for validity testing
- No concerns
- The measure was correlated with SHR and SMR via trend testing. No concerns

2b2-3. Other Threats to Validity (Exclusions, Risk Adjustment) 2b2. Exclusions: Are the exclusions consistent with the evidence? Are any patients or patient groups inappropriately excluded from the measure? 2b3. Risk Adjustment: If outcome (intermediate, health, or PRO-based) or resource use performance measure: Is there a conceptual relationship between potential social risk factor variables and the measure focus? How well do social risk factor variables that were available and analyzed align with the conceptual description provided? Are all of the risk-adjustment variables present at the start of care (if not, do you agree with the rationale provided)? Was the risk adjustment (case-mix adjustment) appropriately developed and tested? Do analyses indicate acceptable results? Is an appropriate risk-adjustment strategy included in the measure?

- No patient group is inappropriately excluded from the measures.
- exclusion criteria do not include those with exhausted vascular access or other potentially appropriate clinical reasons for long-term catheter use (frailty/advanced age)
- Exclusions were appropriate. No risk adjustments.
- Yes
- those with exhausted access options should be excluded. Risk adjustment seems warranted since data suggest that subpopulations perform differently and practitioners could be penalized for caring for large numbers of these subpopulations
- If the physician and staff have had a through discussion with the patient, then should those patients who have decided not to remove a CVC not be excluded?
- see answer above
- only concern (as mentioned initially in the measure) is for those who have exhausted all means of access; if no way to exclude, then the practitioner gets penalized for something out of their control.
- Would query whether nephrology care prior to dialysis (<12 months and >=12 months) would be a possible risk adjuster.
- exclusions appropriate
- 2b2: exclusions are consistent 2b3: N/a
- No concerns

- Exclusions: As previously noted, the measure does not appropriately account for the numerous clinical scenarios laid out in the supporting KDOQI Guidelines in which CVCs may be appropriate. This could result in unintended and adverse events in those patients for whom AV access in not suitable. This issue could be largely remedied with the addition of an exclusion for patients on ESRD treatment <90 days (which would also align the measure with numerous other CMS ESRD metrics), in addition to establishing an "expected percentage" or threshold to allow for a certain anticipated number of patients with exhausted access options.
- Exclusions included area appropriate, but may be inadequate. Specifically, the measure does not exclude individuals without alternative vascular access options. No risk-adjustment.
- Exclusions are consistent.
- Patient choice may need to be considered as it is part of the KDOQI. Also patients with severe cardiac disease may need exclusion as well.

2b4-6. Threats to Validity (Statistically Significant Differences, Multiple Data Sources, Missing Data) 2b4. Meaningful Differences: How do analyses indicate this measure identifies meaningful differences about quality? 2b5. Comparability of performance scores: If multiple sets of specifications: Do analyses indicate they produce comparable results? 2b6. Missing data/no response: Does missing data constitute a threat to the validity of this measure?

- There are no threats to validity. This measure is meaningful because it indicates the use of catheters by gender, race, and age, and can help understand why some patients are utilizing a long-term catheter versus a fistula or graft. The analyses does implement comparable results.
- no concerning threats to validity
- There is a concern for missing data and what was the root cause or comorbids resulting in the missing data.
- No missing data does not constitute a threat to the validity of this measure
- It is not entirely clear that the measure identifies meaningful differences in quality
- No issues
- none
- no
- Outcome of either mortality or hospitalizations differ by about 3-4 per 100 pt-years and 5-6%, respectively, between the lowest 10% and highest 10% categories. With many social determinants of care that cannot be fully modeled yet may influence the outcomes, query if this measure reflects care quality as well as it is being interpreted and used by CMS in the QIP.
- No
- 2b4-6: Moderate threat to validity seems possible due to missing data.
- No concerns raised by the SMP
- Meaningful Differences: The measure does not appear to sufficiently discriminate performance. An essential component of NQF's evaluation of validity is a demonstration of meaningful differences in performance, allowing patients to make informed decisions about the quality of care delivered by providers. For NQF 3567, CMS testing data indicate that approximately 90% of all clinicians and clinician groups perform "as expected." A performance measure in which 90% of all measured entities are reported as performing "as expected" will provide little meaningful, actionable information to patients, raising the question of whether these data are sufficiently compelling to support the measure's intended use in public reporting. (In contrast, for the facility-level LTCR measure, 75% were categorized as performing "as expected.")
- As above, approach for validity testing needs to be clarified

- No concerns
- The correlation between SMR and SHR with CVC's demonstrates a difference in the quality of care versus those with an AVF or AVG. I am concerned that the disparity data is not included and the measure risk adjusted. Assigning a catheter to a CROWNWEB field that is blank may bias the results.

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.
   - The developer notes that all data elements in defined fields in a combination of electronic sources
   - The developer reports that the data are 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)

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?
- Is the data collection strategy ready to be put into operational use?

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

Committee Pre-evaluation Comments:
Criteria 3: Feasibility

3. **Feasibility: Which of the required data elements are not routinely generated and used during care delivery? Which of the required data elements are not available in electronic form (e.g., EHR or other electronic sources)? What are your concerns about how the data collection strategy can be put into operational use?**
   - There are no concerns.
   - elements seem readily defined and easy to collect
   - I have concerns with the subjectivity of denominator exclusions and manipulation of data. It is not uncommon to see from a survey purview manipulation of data to meet the regulatory requirements.
   - No concerns. All data are generated and used during care delivery
   - No concerns
   - No issues
   - none
   - No concerns re: feasibility
   - No issues with feasibility.
   - all elements routinely generated
   - no concerns
   - elements are collected during typical workflow and reported in discrete fields
   - Preliminary Feasibility Rating: High. Data are easily captured in CROWNWeb and other electronic sources.
   - feasible

- All data elements are defined and are generated and or collected by healthcare personnel during provision of care
- Data is easily gathered from CROWNWEB

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

- The developer noted that the measure is currently undergoing initial endorsement review. The developers mentioned that upon completion of endorsement review, CMS will consider this measure for implementation in public reporting for such programs as Medicare Care Compare and/or the Quality Payment Program. If required by the program, the measure will be submitted to the NQF Measures Application Partnership for review prior to implementation.

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

- N/A

Additional Feedback:

- N/A

Questions for the Committee:

- How have (or can) the performance results be used to further the goal of high-quality, efficient healthcare?

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

- The developers noted that the measure is not yet implemented in a public reporting program, so improvement could not be evaluated. CMS currently anticipates implementation of this catheter measure. Once implemented practitioner performance on the measure can be evaluated to determine if the measure has supported and detected quality improvement in reducing prolonged catheter use, while accounting for patients where a long-term catheter may be an appropriate vascular access choice.

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 [unexpected findings]

Potential harms

- N/A

Additional Feedback:

- N/A

Questions for the Committee:

- How can the performance results be used to further the goal of high-quality, efficient healthcare?

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

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

4a1. Use - Accountability and Transparency: How is the measure being publicly reported? Are the performance results disclosed and available outside of the organizations or practices whose performance is measured? For maintenance measures - which accountability applications is the measure being used for? For new measures - if not in use at the time of initial endorsement, is a credible plan for implementation provided? 4a2. Use - Feedback on the measure: Have those being measured been given performance results or data, as well as assistance with interpreting the measure results and data? Have those being measured or other users been given an opportunity to provide feedback on the measure performance or implementation? Has this feedback has been considered when changes are incorporated into the measure?

- A credible plan is provided.
- not being current used since new measure but potential for use seems apparent
- The measure is new and not yet publicly reported.
- Yes
- NA. New measure
- no issues
- opportunity has been provided
- Not sure
- Yes

- If approved will be used for public reporting.
- 4a1: not currently being reported. I am unaware of implementation of this measure. 4a2: The measure should motivate more providers to improve AV peripheral access establishment to keep their LTC rate low.
- Currently not in use but consideration given to use in the QPP program and or Medicare Care Compare after NQF endorsement
- Preliminary Use Rating: Moderate to high. The developer has provided a credible plan for use.
- Would be helpful to further understand planned use of the measure, not currently in use
- No issue with feasibility
- The measure is a new measure.

4b1. Usability – Improvement: How can the performance results be used to further the goal of high-quality, efficient healthcare? If not in use for performance improvement at the time of initial endorsement, is a credible rationale provided that describes how the performance results could be used to further the goal of high-quality, efficient healthcare for individuals or populations? 4b2. Usability – Benefits vs. harms: Describe any actual unintended consequences and note how you think the benefits of the measure outweigh them.

- None
- Potential for measure to improve quality of healthcare deliver -- though there is need to consider how to exclude those without vascular access options or those for whom AVF/AVG may truly not be best access from the measure
- The goal to understand individual and group practice is necessary. However I do have concerns regarding other factors such as surgical resources in the region. Facility process to lower CVCs rates - for example: breaching cannulation protocol for the purpose of lowering CVCs.
- No unintended consequences
- Yes
- Given the narrowing gap, and patient preference, there may be an unintended consequence where metric achievement overcomes patient preference
- potential unintended consequence: Patients with long term catheters or limited fistula/graft accesses may be denied acceptance for care by providers due to negative consequences of measure. Patients may conceivable be "pushed " to having procedures that they do not wish to undergo , both of these may be difficult to track and quantify
- This will serve to push practitioners to encourage patients to get AVF/AVG. Benefit is improved dialysis, less infection risk.
- Given the recent update of the NKF on HD vascular access, in particular the attention to more individualized care, this measure may push healthcare providers towards obtaining vascular access in patients with reduced life expectancy or quality of life.
- If approved will be used for public reporting.
- 4b2: the benefits outweigh the possible harm. Elderly or patient with multiple co-morbid may have multiple surgeries to provide a peripheral access. These multiple surgeries can be a risk.
- No unintended consequences expected
- Preliminary Usability Rating: Moderate. An important component of NQF's Usability criterion is an assessment of benefits vs. harms, which was not provided by the developer. Again, the measure only accounts for patients with limited life expectancy, not addressing other patients for whom a LTC is a more appropriate access choice and pursuit of a fistula may be deleterious. The measure could be strengthened with the addition of an exclusion for patients on ESRD treatment <90 days to account for many of these patients; the exclusion would also align the measure with numerous other QIP metrics.

Likewise, establishing an "expected percentage" or threshold to allow for a certain anticipated number of patients with truly exhausted access would strengthen the measure.

- Potential for unintended consequences given incomplete exclusions and lack of risk-adjustment
- Rationale provided for potential to be used for medicare care compare and/or quality payment program
- A decrease in catheter rates will decrease health care costs and improve quality of life for patients by decreasing infections and possible hospitalizations. An unintended consequence is the additional surgery required to transpose upper arm AVF's in order to use. It is important to consider patient choice which may lead to more catheters if patients don't understand the risk of catheters.

Criterion 5: Related and Competing Measures

Related or competing measures

The developer identified the following measure as related:

- 2977 : Hemodialysis Vascular Access: Standardized Fistula Rate (endorsement removed)
- 2978 : Hemodialysis Vascular Access: Long-term Catheter Rate

Harmonization

- The developer indicated that the measures have been harmonized.

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

5. Related and Competing: Are there any related and competing measures? If so, are any specifications that are not harmonized? Are there any additional steps needed for the measures to be harmonized?

- There are no additional steps needed.
- no readily apparent related/competing measures or necessary additional steps
- Yes, but these measures are harmonized.
- Yes other measures. The measure specifications are harmonized with related measures.
- Long-term catheter rates are already being reported at the facility level; this measure largely duplicates the facility level data
- Existing measures have been harmonized
- facility measure is harmonized with current measure as presented
- Looks to be harmonized
- No
- Harmonized.
- Yes, as listed 2977 and 2978. The measures are harmonized.
- measure has been harmonized with the additional 2 measures noted on the measure worksheet
- NQF 2977 Hemodialysis Vascular Access: Standardized Fistula Rate and NQF 2978 Hemodialysis Vascular Access: Long-term Catheter Rate are listed by the developer as related measures. Specifications are harmonized.
- Measures have been harmonized by developer
- There are 2 other measures 2977 and 2978 which have been harmonized

Public and Member Comments

Comments and Member Support/Non-Support Submitted as of: 01/15/2021

- Comment by: Kidney Care Partners

  Kidney Care Partners (KCP) appreciates the opportunity to submit early (pre-Standing Committee meeting) comments on the measures under consideration for endorsement in the National Quality Forum's Renal Project Fall 2020 Cycle. KCP is a coalition of members of the kidney care community that includes the full spectrum of stakeholders related to dialysis care—patient advocates, healthcare professionals, dialysis providers, researchers, and manufacturers and suppliers—organized to advance policies that improve the quality of care for individuals with both chronic kidney disease and end stage renal disease. We commend NQF for undertaking this important work and offer comment on both measures under review. KCP believes vascular access may be the most important performance metric for patients making decisions about dialysis facilities and has consistently supported the facility-level Long-Term Catheter Rate (LTCR) measure, NQF 2978. Nevertheless, in reviewing the clinician-level LTCR measure we have identified a number of issues that warrant consideration and offer the following substantive and technical comments:

- Meaningful Differences in Performance. An essential component of NQF's evaluation of validity is a demonstration of meaningful differences in performance, allowing end-users of public reporting or value-based purchasing programs to make informed decisions about the quality of care delivered by various providers. For the practitioner-level LTCR measure, CMS testing data indicate that approximately 90% of all clinicians and clinician groups perform "as expected." We disagree with CMS's conclusion that these data demonstrate the measure identifies practical differences in performance. A performance measure in which 90% of all measured entities are reported as performing "as expected" provides little meaningful, actionable information to patients, and we do not find the above statistics sufficiently compelling to support the measure's intended use in public reporting.
- Permanent Access Maturation. KCP believes catheter reduction is paramount, but we again note arteriovenous fistulas frequently require two to three months to reach maturity. We thus believe an exclusion for patients on ESRD treatment <90 days as of the first day of the reporting month would strengthen the measure considerably. This revision would minimize the risk of penalizing providers for physiological circumstances beyond their control and would also align NQF 3567 with the numerous CMS NQF-endorsed facility-level measures containing this exclusion.
- Patients on Transplant Waitlists. Given the burden associated with arteriovenous fistula placement on both patients and health resources, nephrologists may determine short-term vascular access options may be more appropriate for new dialysis patients already on the transplant waitlist whose waiting time is expected to be brief, such as with a living related donor transplant. Here again, an exclusion for patients on ESRD treatment <90 days as of the first day of the reporting month would largely effectively address this issue.
- Patients with Exhausted Vascular Access Options. CMS notes in its measure submission materials that a Vascular Access TEP it convened in 2015 had favored a measure exclusion for patients who have exhausted their anatomic vascular access options, verified by documentation of a second opinion from a qualified vascular access surgeon, but was unable to reach consensus on how best to incorporate it. While operationalizing this exclusion may indeed prove challenging, we agree with the TEP that the continued pursuit of permanent access in patients for whom this is no longer a viable option is a considerable risk in its absence. We urge the developer to revisit the TEP's recommendation to assess for a reliable, valid means of capturing of this important clinical data point. An alternative approach would be to establish an "expected percentage" or threshold to allow for a certain anticipated number of patients with truly exhausted access.

- Profile Inter-Unit Reliability (PIUR). KCP has consistently opposed CMS's use of the PIUR for accountability metrics intended to distinguish performance between providers. CMS and UM-KECC crafted this novel metric of reliability to "assess more directly the value of performance measures in identifying facilities with extreme outcomes."[1] Per CMS: "The PIUR indicates the presence of outliers or heavier tails among the providers, which is not captured in the IUR itself. . . . [When] there are outlier providers, even measures with a low IUR can have a relatively high PIUR and can be very useful for identifying extreme providers." KCP strongly concurs, however, with NQF's Scientific Methods Panel (SMP) conclusion that the PIUR is not an appropriate reliability metric for measures in any accountability program intended to distinguish performance between providers falling in the middle of the curve, along a continuum. The ability to reliably distinguish outliers is inconsistent with the purpose of such programs, and the SMP concluded the IUR is and remains the appropriate reliability statistic for this purpose. While in this instance the measure's IURs are acceptable, KCP on principle reiterates its general opposition to use of the PIUR to demonstrate reliability in accountability metrics used in programs intended to distinguish performance along a curve.
- Attribution Rules Clarification. In the measure specifications CMS defines "long-term catheter use" as occurring under the care of the same practitioner or group practice for at least three consecutive months as of the last hemodialysis session of the reporting month. Measure submission materials further clarify that "counting" for the measure restarts if a patient transfers to a different practitioner/group, but this detail is not included in the formal measure specifications. KCP suggests the developer add an exclusion or revise the denominator to explicitly clarify this point.
- Small Numbers Exclusion, Typographical Error. We note CMS indicates in the measure submission materials that when used for public reporting, measure calculation "will be restricted to facilities with at least 11 patients in the reporting month to ensure patients cannot be identified due to small cell size." As language elsewhere in the materials indicate the restriction applies to practitioners or practitioner groups, as is consistent with the focus of the measure, we believe the reference to facilities was a typographical error and request confirmation and correction from the developer.

_____

[1] Kalbfleisch JD, He K, Xia L, Li Y. Does the inter-unit reliability (IUR) measure reliability? Health Services and Outcomes Research Methodology. 2018;18(3):215-225. Doi: 10.1007/s10742-018-0185-4.

- Of the 1 NQF member who have submitted a support/non-support choice:
  - 0 support the measure
  - 1 do not support the measure

Combined Methods Panel Scientific Acceptability Evaluation

Scientific Acceptability: Preliminary Analysis Form
Measure Number: 3567
Measure Title: Hemodialysis Vascular Access: Practitioner-Level 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**

Data Source:

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

Panel Member #1: IDR Medicare Provider table selected for MCPs
Panel Member #4: IDR Medicare Provider table selected for MCPs
Panel Member #8: Medicare provider file

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** Panel Member #3: I'm not sure, measure seems similar to 0256 Minimizing use of catheters…**(**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 #4: No concerns

   Panel Member #5: No concerns

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 VALIDITY testing** of **patient-level data** conducted?

   ☐ **Yes** ☒ **No**

6. **Assess the method(s) used for reliability testing Submission document:** Testing attachment, section 2a2.2 Used an appropriate method.

   Panel Member #1: Used an appropriate method.

   Panel Member #3: Developers estimate reliability for measures reported at two levels, practitioners and practitioner groups. Analyses are based on data from providers who have at least 11 eligible patients during the reporting period. Reliability is quantified by two metrics : (1) inter unit reliability (IUR) which is the conventional proportion of signal variation definition of reliability and (2) profile inter unit reliability (PIUR) which is a relatively recent method.

   IUR is estimated using a nonparametric approach that combines bootstrap sampling with ANOVA formulas. I have no questions or concerns about this method.

   The PIUR addresses how well a measure can identify providers in the tails of the performance distribution but the interpretation is not straightforward. Conceptually, it involves identifying providers who have scores above a threshold (i.e. low performance) and then calculating the proportion of these

providers who would have scores above this threshold again if performance was re-estimated in a different random sample of patients from the same provider-specific patient population while holding each provider's underlying true performance fixed. After determining this "reflagging probability" quantity, the PIUR is calculated as the value of IUR that would yield this reflagging probability in a hypothetical measurement scenario in which true and estimated performance values are distributed according to a random effects model with normally distributed true performance values. If this type of hierarchical model is a good approximation of truth, then IUR and PIUR would be estimating the same quantity and so whatever threshold numerical value corresponds to "acceptable reliability" for IUR results could also be applied when evaluating PIUR results. However, the motivation for using PIUR is the assumption that true performance is not normally distributed e.g. the number of providers with extremely high or low true performance may be higher than what would be expected under a normal distribution. When the PIUR is applied to datasets in which true performance is non-normal, my impression is that it cannot be interpreted as estimating the same quantity as the IUR (i.e. it is not estimating the squared correlation between true and estimated values or the proportion of signal variation), and the true PIUR may be much higher than the true IUR. Because the PIUR is not in general interpretable as an IUR and because it does not appear to have another simple or direct interpretation, this raises the question of how to determine what PIUR value corresponds to "acceptable reliability". I focused on IUR more than PIUR in my evaluation because that's a quantity that I'm able to interpret.

For both methods, the reported metric is a single number that describes overall reliability across the range of provider sample sizes. Statistical precision will obviously vary depending on sample size. This raises the question of how developers arrived at a minimum sample size of 11 eligible cases for public reporting.

Panel Member #4: Inter-unit reliability (to measure the proportion of variation of a measure that is attributable to the between practitioner variation which reflects the differences across practitioners) and profile IUR (to assess the measure ability to consistently flag the same provider) were calculated.

These measures seem appropriate to me.

Panel Member #5: The reliability test is appropriate in regard to measure score testing.

- one-way analysis of variance (ANOVA), in which the between-practitioner variation (σ_b^2) and the within-practitioner 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-practitioner variation, the true signal reflecting the differences across practitioners'
- IUR near 0 reveals that most of the variation of the measures between practitioners is driven by random noise
- IUR near 1 indicates that most of the variation between practitioners is due to the real difference between practitioners' [p5]

Panel Member #6: IUR and profile IUR statistics were calculated for physicians and physician groups.

Panel Member #7: The cited "NQF-recommended approach" as a one-way ANOVA I am not convinced is accurate. Although IUR and PIUR methods for assessing reliability appear to adequately assess between unit variation, I am concerned that those methods underestimate the within facility variation (bias), inflating the reliability estimate and introduce correlated error. It would be helpful to have seen a parallel ICC analysis of their data.

Panel Member #8: The developer assessed the measure score reliability at both practitioner and practitioner group level by calculating inter unit reliability and profile inter unit reliability which is more suited for identifying extreme outliers. These approaches are conceptually similar to other reliability calculations.

Panel Member #9: Methods were appropriate for assessing measure score-level reliability.

7. **Assess the results of reliability testing**

Submission document: Testing attachment, section 2a2.3

Panel Member #1: No issues.

Panel Member #3: Estimated IURs were 0.602 for practitioners and 0.793 for practitioner groups.

Estimated PIURs were 0.804 for practitioners and 0.815 for practitioner groups.

Panel Member #4: The developer writes "The IUR at **practitioner level** indicates that 60.2% of the variation in the annual long-term catheter rate can be attributed to between-practitioner differences in performance (signal) and 39.8% to the within-practitioner variation (noise). This value of IUR implies a **moderate degree of reliability**. The higher PIUR compared to the IUR indicates the **presence of outliers** or heavier tails among the providers, which is not captured in the IUR itself. If there are no outliers, one should expect the PIUR to be similar to the IUR; but in cases where there are outlier providers, even measures with a low IUR can have relatively high PIUR and can be very useful for identifying extreme providers.

The IUR at practitioner **group level** indicates that 79.2% of the variation in the annual long-term catheter rate can be attributed to between-group differences in performance (signal) and 20.7% to the within-group variation (noise). This value of IUR implies a **high** degree of reliability."

This seems reasonable to me.

Panel Member #5: In general, the reliability testing results is modest, but acceptable for measure score testing.

- The IUR at practitioner level is 0.602. The PIUR at the practitioner level is 0.804.
The IUR at practitioner group level is 0.793. The PIUR at the practitioner group level is 0.815.' [p7]

Panel Member #6: IUR values were 0.6 and 0.8 for physicians and physician groups, respectively, while profile IUR values were equal to 0.8 for both physicians and physician groups.

Panel Member #7: The practitioner level results are less robust than the group level results.

Panel Member #8: The results of both IUR and PIUR are above 0.6 at practitioner level and above 0.79 at practitioner group level. These results indicate acceptable reliability.

Panel Member #9: Reliability at the measure score level was adequate, particularly using the PIUR statistic focusing on the ability of the measure to identify extreme outliers**.**

In general, the reliability testing results is modest, but acceptable for measure score testing.

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: IUR value implies a high degree of reliability at practitioner and group level.

    Panel Member #3: Moderate based on the estimated IUR of 0.60 for practitioners.

    Panel Member #4: No additional concerns.

    Panel Member #5: As noted in Q7: In general, the reliability testing results is modest, but acceptable for measure score testing.

    Panel Member #6: The profile IUR statistics indicate that outliers can be reliably flagged. In general, I find the reliability of the measure at the physician group level to be moderate to high, and from a conceptual standpoint, management of the vascular access at the physician group is logical.

    Panel Member #7: I am concerned that the reliability estimates at the practitioner level fall below what would be needed for fair comparisons at the individual level.

    Panel Member #8: IUR is above 0.6 at practitioner level and above 0.79 at practitioner group level. PIUR is even higher for both levels, respectively.

    Panel Member #9: The IUR statistic for the measure's ability to identify differences among entities was acceptable – the PIUR statistic for the measure's ability to identify extreme outliers was high. Since the measure cannot be endorsed just for the latter purpose, I chose "moderate" as the overall assessment.

VALIDITY: ASSESSMENT OF THREATS TO VALIDITY

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

    Submission document: Testing attachment, section 2b2.

    Panel Member #1: None.

    Panel Member #3: None

    Panel Member #4: The exclusions seem rational and to have minimal impact.

    Panel Member #6: The impact of exclusions on sample size is small. The exclusions themselves are logical. Thus, I have no concerns.

    Panel Member #8: No concern.

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: None

    Panel Member #3: None

    Panel Member #4: I cannot tell from the analysis provided if there is a sufficient spread of values.

    Panel Member #5: No concerns

Panel Member #6: The measure identifies approximately 10% of physicians and physician groups as having significantly higher than expected rates of long-term catheter utilization.

Panel Member #9: As noted above, and as noted by the developers, the measure is better at identifying extreme outliers (particularly at the low end of the distribution) than for identifying differences within the main body of the distribution**.**

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 #1: N/A
Panel Member #3: N/A Panel Member #4: N/A
Panel Member #5: No concerns.
Panel Member #6: This is not applicable
Panel Member #8: No concerns.

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

Submission document: Testing attachment, section 2b6.

Panel Member #1: None.

Panel Member #3: None

Panel Member #4: No concerns

Panel Member #5: No concerns, but given only 1.8% of the data has a missing value it seems it would have been best to remove such data from the ratings (but it remained in the data set). Panel Member #6: I have no concerns

Panel Member #8: No concern.

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 #4: The developer states that the TEP did not recommend using.

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

Panel Member #5: NA – measure not risk adjusted & thus no social risk factors used

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

16d. **Risk adjustment summary:**

16d.1 All of the risk-adjustment variables present at the start of care? ☒ Yes ☐ No
Panel Member #5: NA – measure not risk adjusted
16d.2 If factors not present at the start of care, do you agree with the rationale provided for inclusion?
☐ Yes ☒ No
Panel Member #1: N/A
Panel Member #5: NA – measure not risk adjusted
16d.3 Is the risk adjustment approach appropriately developed and assessed? ☒ Yes ☒ No
Panel Member #5: NA – measure not risk adjusted
16d.4 Do analyses indicate acceptable results (e.g., acceptable discrimination and calibration)
☒ Yes ☒ No

Panel Member #5: NA – measure not risk adjusted

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

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

Panel Member #1: Based on the prior approach of similar measures, this approach is adequate.

Panel Member #3: The developers argue that adjustment is not appropriate because the main goal is to disincentive use of catheters. A TEP that was convened for this measure also did not recommend adjustment. I don't oppose the developer's rationale but it seems to raise a philosophical issue. Should the goal of incentivizing provider behavior take priority over the goals of optimizing validity and creating a level playing field across providers?

Panel Member #4: I'm conflicted about this as there is no risk adjustment presented (which might show differences better) but I worry that not behaving a risk adjustment model. will penalize some providers taking care of those at risk (the usual risk adjustment argument)**.** This is especially important as the developer provides evidence suggesting that there are differences in age, gender, race, ethnicity and employment status and several other variables (if I correctly understand their submission). On the other hand, the dialysis facility measure is not risk adjusted. and it would make sense to harmonize these measures.

Panel Member #5: The rationale for not employing risk adjustment is reasonable. Additionally, as the measure steward pointed out, several of the exclusions in the measure mitigate the need for risk adjustment.

Panel Member #6: Risk adjustment for vascular access type in dialysis patients is highly controversial**.** I have an opinion about this topic, too, but I acknowledge that the measure steward has adopted a defensible position.

Panel Member #7: The data provided suggest that multiple patient characteristics are significantly associated with the odds of long-term catheterization and should be considered in a risk adjustment model.

Panel Member #8: The developer provided rationale on why this measure should not be risk adjusted.

Panel Member #9: The decision to not do risk adjustment if the measure is indeed a process measure, and all patients should be treated in the same way. I believe that this is a process measure and that the absence of risk adjustment is acceptable. However, the developers claim that this is an intermediate outcome measure, suggesting that some patient characteristics may create a clinical need for catheter placement. If this is true, then the risk adjustment approach is not adequate, and that those factors that have a statistical relationship with catheter use that are present at the start of care and have a relationship with the "outcome" should at least be considered for risk adjustment, and probably included in a risk-adjustment model.**.**

For cost/resource use measures ONLY: Panel Member #5: NA – not a cost / resource use measure

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

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

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

VALIDITY: TESTING

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

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

    ☐ **Face validity**

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

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

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

Submission document: Testing attachment, section 2b2.2

Panel Member #1: Appropriate

Panel Member #3: Developers compared mortality and hospitalization rates across groups of practitioners ranked by their rates of catheter access. It wasn't clear to me whether mortality and hospitalization rates were risk-adjusted and I wondered is such an adjustment would impact conclusions.

Panel Member #4: "Validity was assessed using the trend test to measure the association between practitioner level long-term catheter rates occurring in January-December 2016 and hospitalization and mortality in the following 12 months. A similar validity analysis was performed for the practitioner group level long-term catheter rates." This seems appropriate albeit minimalistic.

Panel Member #5: The validity testing method is reasonable for measure score level testing. '…association between practitioner level long-term catheter rates and hospitalization and mortality in the following 12 months' [p8]

Panel Member #6: Mortality and hospitalization rates were correlated with the measure.

Panel Member #7: There is insufficient detail in the methods section to assess the adequacy of the approach used.

Panel Member #8: The developer assessed the validity of measure score by first dividing the facilities into three categories, top 10%, middle 80%, and bottom 10%. The developer then assessed if mortality and hospitalization rates are associated with the three categories in an expected direction.

Panel Member #9: The primary method for validity analysis involves comparing units with different levels of measure performance on a measure of mortality. This is not a particularly strong or compelling approach to validity, but in a context where there is clinical consensus on the inappropriateness of long-term catheter use, this may be acceptable. This concern is magnified if the measure is indeed an intermediate outcome measure as the developers claim. If it is a process measure, then the level of concern is lower.

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

Submission document: Testing attachment, section 2b2.3

Panel Member #1: Appropriate

Panel Member #3: Rates of mortality and hospitalization increased across categories of providers with increasing catheter rates.

Panel Member #4: The developers state "Result of the trend test for the lowest 10% and highest 10% categories (reference is the middle 80% category) suggests higher long-term catheter use is associated with both higher all-cause hospitalization and mortality at both the practitioner level and the practitioner group level."

This seems appropriate albeit minimalistic.

Panel Member #5: The validity testing results are strong for both individual clinician and group level measurement.

Practitioner Level

Mortality rates are 17.0, 18.4 and 20.8 (per 100 patient-years) for practitioners having long-term catheter rates falling into the lowest 10%, middle, and highest 10% categories respectively ($p<0.001$).

Percentages of patient hospitalization (all-cause) are 60.8%, 62.8% and 67.8% for practitioners having long-term catheter rates falling into the lowest 10%, middle, and highest 10% categories respectively ($p<0.001$).

Practitioner Group Level

Mortality rates are 18.4, 18.3 and 21.3 (per 100 patient-years) for practitioner-groups having long-term catheter rates falling into the lowest 10%, middle, and highest 10% categories respectively ($p<0.001$).

Percentages of patient hospitalization (all-cause) are 61.9%, 62.9% and 67.6% for practitioner-groups having long-term catheter rates falling into the lowest 10%, middle, and highest 10% categories respectively ($p<0.001$).' [p8]

Panel Member #6: Both mortality and hospitalization rates were positively correlated with the measure, albeit modestly.

Panel Member #7: At the practitioner and group levels, the differences between those with catheter rates at the highest and lowest deciles for mortality rates are very small (3.8% and 2.9% respectively) and roughly 7% for similar comparisons of all-cause hospital admissions.

Panel Member #8: At both practitioner and practitioner group level, the developer found that higher long term catheter use is associated with higher mortality and hospitalization.

Panel Member #9: There is a significant relationship between catheter use and mortality in the expected direction, but the relationship is not strong**.**

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

    Panel Member #9: As noted above, the conceptual link between catheter use and mortality at the practice or individual provider level is fairly weak, but plausible. Therefore, a correlation does speak to measure validity, but the strength of inference about validity cannot be high**.**

    Submission document: Testing attachment, section 2b1.

    ☒ **Yes**

    ☒ **No**

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

23. **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)

24. **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.)

25. **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: Association of higher long-term catheter use and higher all-cause hospitalization and mortality at both the practitioner level and the group level.

Panel Member #4: I gave this rating as I think this approach was too simplistic and minimalistic.

Panel Member #5: As noted in Q22: The validity testing results are strong for both individual clinician and group level measurement.

Panel Member #6: It appears that high long-term catheter utilization is associated with elevated rates of death and hospitalization, as one would expect. Whether this reflects a causal effect of catheter dependence is unclear. An analysis of infectious complication would be potentially more relevant than all-cause death and hospitalization.

Panel Member #7: There was little detail in the approach used to assess the appropriateness of the methods.

Panel Member #8: The measure score is found to be associated with other indicators in an anticipated fashion.

Panel Member #9: This was a difficult decision between moderate and low, and I chose moderate because I feel that the measure should pass validity, even with a limited and weak body of evidence on validity. There is a high level of face validity to the measure as a process measure, and the developers should receive some credit for not just relying on that, but going ahead to do some test of empirical validity.

FOR COMPOSITE MEASURES ONLY: Empirical analyses to support composite construction

26. **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**

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

ADDITIONAL RECOMMENDATIONS

28. **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 #5: No substantive concerns.

    Panel Member #9: As noted above, the developers claim that this is an intermediate outcome measure, without going into any detail about what underlying care process lead to this as an outcome. It really seems to be a process measure, and my evaluation is based on it being really a process measure. If it IS an outcome measure, then the absence of risk adjustment is not acceptable**.**

Brief Measure Information

NQF #: 3567

Corresponding Measures:

De.2. Measure Title: Hemodialysis Vascular Access: Practitioner Level 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 attributable to an individual practitioner or group practice.

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

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 under the care of the same practitioner or group partner.

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 for any portion of the reporting month
- Patient-months where there are more than one MCP provider listed for the month.

In addition, patients with a catheter that have limited life expectancy, as defined by the following criteria are excluded:

- 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

This measure does not exclude patients who have exhausted their vascular access options. A 2015 Technical Expert Panel had robust discussion about trying to add this to a facility-level catheter measure, but was unable to reach consensus about how best to incorporate such an exclusion criteria.

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

S.17. Data Source: Claims, Registry Data

S.20. Level of Analysis: Clinician : Group/Practice, Clinician : Individual

IF Endorsement Maintenance – Original Endorsement Date: Most Recent Endorsement Date:

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?

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

PhysLTC_evidence-637405276854753547.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.

1a. Evidence (subcriterion 1a)

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

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

IF the measure is a component in a composite performance measure, provide the title of the Composite Measure here:

Date of Submission:

1a.1. This is a measure of: (*should be consistent with type of measure entered in De.1*)

Outcome

☐ Outcome:

- ☐ Patient-reported outcome (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:

- ☐ Appropriate use measure:

☐ Structure:

☐ Composite:

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 among patients at a physician group practice.

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.

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

When this measure was originally developed and specified, 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 (e.g., severe arterial occlusive disease, non-correctable 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 long-term vascular access events (e.g., 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 (e.g., infection, thrombotic, and non-thrombotic 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, physician level 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.

Systematic Review	Evidence
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

Systematic Review	Evidence
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 at the end of this document. 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	**Strong** - Evidence includes results from well-designed, well-conducted study/studies in the target population that directly assess effects on health outcomes.

Systematic Review	Evidence
	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. See table at the end of this document for a grading matrix
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. National Kidney Foundation. KDOQI Clinical Practice Guidelines and Clinical Practice Recommendations for 2006 Updates: Hemodialysis

Systematic Review	Evidence
	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
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.

Systematic Review	Evidence
	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

Systematic Review	Evidence
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?	The studies listed below continue to highlight the increased morbidity and mortality associated with long term catheter use relative to either AVF or AVG. While these studies do not change the overall conclusions of the Systematic Review described above, they do highlight the recognition that a catheter avoidance strategy may be more important than whether a patient has an AVF or an AVG created. Specifically, some of the studies below report that for patients who are older, or have other factors associated with a lower chance of AVF maturation, that an AVG may function as well as an AVF. The most recent literature below highlights that some of the increased mortality associated with long term catheters may have been overstated in earlier studies. When taken together, the recently published studies outline some of the more nuanced medical decision making that is required when counseling patients and creating long term vascular access for dialysis patients. 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.* 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. Mortality compared 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). 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

Systematic Review	Evidence
	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. Impact: Underscores that patient factors and comorbidities account for some of the mortality benefit that has traditionally been ascribed to using and AVF for vascular access. Rivara MB, Soohoo M, Streja E, et al. **Association of Vascular Access Type with Mortality, Hospitalization, and Transfer to In-Center Hemodialysis in Patients Undergoing Home Hemodialysis.** *Clin J Am Soc Nephrol. 2016 Feb 5;11(2):298-307. doi: 10.2215/CJN.06570615. Epub 2016 Jan 4.* This study examined the associations of vascular access type with all-cause mortality, hospitalization, and transfer to in-center HD in patients who initiated home HD from 2007 to 2011 in 464 facilities in 43 states in the US. Data were analyzed using competing risks hazards regression, with vascular access type at the start of home HD as the primary exposure in a propensity score-matched cohort (1052 patients; 526 with CVC and 526 with arteriovenous access). Compared with arteriovenous access use, CVC use was associated with higher risk for mortality (hazard ratio, 1.73; 95% confidence interval, 1.18 to 2.54) and hospitalization (hazard ratio, 1.19; 95% confidence interval, 1.02 to 1.39). CVC use was not associated with increased risk for transfer to in-center HD. The results of analyses in the entire unmatched cohort (2481 patients), with vascular access type modeled as a baseline exposure at start of home HD or a time-varying exposure, were similar. Analyses among a propensity score-matched cohort of patients undergoing in-center HD also showed similar risks for death and hospitalization with use of CVCs. CONCLUSIONS: In a large cohort of patients on home HD, CVC use was associated with higher risk for mortality and hospitalization. Impact: Extends the findings of increased hospitalization and mortality associated with long term catheters to the home hemodialysis patient population, who often tend to be younger and healthier than in-center hemodialysis patients. Lee T, Qian J, Thamer M, Allon M. **Tradeoffs in Vascular Access Selection in Elderly Patients Initiating Hemodialysis With a Catheter.**

Systematic Review	Evidence
	Am J Kidney Dis. 2018 May 18. pii: S0272-6386(18)30634-6. doi: 10.1053/j.ajkd.2018.03.023. [Epub ahead of print] This retrospective cohort study evaluated clinically relevant vascular access outcomes in elderly patients receiving an AVF or AVG after hemodialysis therapy initiation. Data: Claims data from the US Renal Data System of 9,458 US patients 67 years and older who initiated hemodialysis therapy from July 1, 2010, to June 30, 2011, with a catheter and received an AVF (n=7,433) or AVG (n=2,025) within the ensuing 6 months. Unsuccessful use of vascular access within 6 months of creation was higher for AVFs versus AVGs (51% vs 45%; adjusted HR, 1.86; 95% CI, 1.73-1.99). Interventions to make vascular access functional were greater in AVFs versus AVGs (42% vs 23%; OR, 2.66; 95% CI, 2.26-3.12). AVFs had a lower 1-year abandonment rate after successful use compared with AVGs (OR, 0.71; 95% CI, 0.62-0.83) and required one-fourth fewer interventions after successful use (relative risk, 0.75; 95% CI, 0.69-0.81). Patients receiving an AVF had substantially longer catheter dependence before successful use than those receiving an AVG (median time, 3 vs 1 month; P<0.001). CONCLUSIONS: In elderly hemodialysis patients initiating hemodialysis therapy with a catheter, the optimal vascular access selection depends on tradeoffs between shorter catheter dependence and less frequent interventions to make the vascular access (AVG) functional versus longer access patency and fewer interventions after successful use of the vascular access (AVF). Impact: Describes the complex tradeoff of selecting AVF vs. AVG in elderly hemodialysis patients. 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

Systematic Review	Evidence
	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.

Systematic Review	Evidence
	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

Systematic Review	Evidence
	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.

Systematic Review	Evidence
	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,

Systematic Review	Evidence
	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

Systematic Review	Evidence
	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.

Systematic Review	Evidence
	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

Systematic Review	Evidence
	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.

_____

1a.4 OTHER SOURCE OF EVIDENCE

If source of evidence is NOT from a clinical practice guideline, USPSTF, or systematic review, please describe the evidence on which you are basing the performance measure.

1a.4.1 Briefly SYNTHESIZE the evidence that supports the measure. A list of references without a summary is not acceptable.

N/A

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

N/A

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

N/A

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.*

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

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

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.*

Using the data from Jan-Dec 2016, age, sex, race, ethnicity and dialysis vintage were evaluated in a logistic regression model for long-term catheter use. Below we report the odds ratios for these patient characteristics. Age, sex, race, ethnicity and dialysis vintage are all statistically significant predictors of long-term catheter use. The analysis results indicate potential disparity in prolonged use of a tunneled catheter among these groups. Specifically, females are about 33% more likely to have a long-term catheter as males. Individuals 75 years of age and older were 13% more likely to have a long-term catheter and younger individuals 18-25 years of age were 43% more likely to have a long-term catheter when compared to patients 60-75 years of age. Those whose race is reported as "Other" were less likely to have a long-term catheter when compared to whites, as were Hispanics, when compared to non-Hispanics. In the absence of biological effects explaining these differences, risk adjustment for these demographic factors could potentially mask disparities in care.

Odds ratio of having a catheter for at least three months:

Age:

For the 18-<25 age group, the Odds Ratio is 1.43, P-value is <. 0001.

For the 25-<59 age group, the Odds Ratio is 1.08, P-value is <.0001.

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

For the 75+ age group, the Odds Ratio is 1.13, P-value is <.0001.

Sex:

For Female: The Odds Ratio is 1.33, and the P-value is <.0001.

Male was used as the reference group.

Race:

White was used as the reference group.

For Black: The Odds Ratio is 0.88, and the P-value is <.0001.

For Other: The Odds Ratio is 0.92, and the P-value is <.0001.

Ethnicity:

For Hispanic: The Odds Ratio is 0.76, and the P-value is <.0001.

Non-Hispanic was used as the reference group.

Employment Status:

Employed was used as the reference group.

For Unemployed: The Odds Ratio is 1.22, and the P-value is <.0001.

For Other: The Odds Ratio is 1.40, and the P-value is <.0001.

Medicare Coverage:

Medicare as primary w/o Medicaid was used as the reference group.

Medicare as primary with Medicaid: The Odds Ratio is 1.08, and the P-value is <.0001.

Medicare as secondary/Medicare HMO: The Odds Ratio is 0.82, and the P-value is <.0001.

For Non-Medicare/missing: The Odds Ratio is 0.76, and the P-value is <.0001.

ADI (zipcode-level):

Unemployment rate (%): The Odds Ratio is 1.00, and the P-value is 0.07.

Median family income: The Odds Ratio is 0.99, and the P-value is 0.28.

Families below the poverty level (%): The Odds Ratio is 1.01, and the P-value is 0.09.

Single-parent households with children <18 (%): The Odds Ratio is 0.996, and the P-value is <.0001.

Home ownership rate (%): The Odds Ratio is 0.997, and the P-value is <.0001.

Median home value: The Odds Ratio is 0.99, and the P-value is 0.26.

Median monthly mortgage: The Odds Ratio is 1.07, and the P-value is 0.02.

Median gross rent: The Odds Ratio is 1.05, and the P-value is 0.20.

Population (aged 25+) without High School diploma (%): The Odds Ratio is 1.00, and the P-value is 0.69.

Income disparity: The Odds Ratio is 1.01, and the P-value is 0.09.

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):*

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):*

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**:** PhysLTC_DataDictionary.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.

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

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.*

***IF an OUTCOME MEASURE**, 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)

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

Long-term catheter use is defined as using a catheter, under the care of the same practitioner or group practice, for at least three consecutive months as of the last day of each 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) under the care of the same practitioner or group partner, 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 the measure is being calculated at the practitioner level and a patient changes to a different practitioner, the counting of the three consecutive complete months restarts for the new practitioner. If the measure is being calculated at the group practice level, and the patient changes to a different group practice, the counting of the three consecutive months restarts for the new group practice.

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 under the care of the same practitioner or group partner.

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.)*

IF an OUTCOME MEASURE*, 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 who received the monthly capitated payment (MCP) by using Medicare physician claims. A shared active Tax Identification Number (TIN) was used to identify group partners. Medicare dialysis claims are used to identify patients that are receiving in-center or home hemodialysis for the entire reporting month.

Assignment to a practitioner for the reporting month required 1) A single Medicare capitated payment (MCP) recipient for the reporting month and 2) the patient modality being in center or home hemodialysis for the entire month and 3) the patient be at least 18 years old as of the first day of the month.

The monthly patient count with a practitioner 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 for any portion of the reporting month
- Patient-months where there are more than one MCP provider listed for the month.

In addition, patients with a catheter that have limited life expectancy, as defined by the following criteria are excluded:

- 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

This measure does not exclude patients who have exhausted their vascular access options. A 2015 Technical Expert Panel had robust discussion about trying to add this to a facility-level catheter measure, but was unable to reach consensus about how best to incorporate such an exclusion criteria.

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 Medicare ESRD facility dialysis claims. Medicare physician supplier claims were used to determine patient assignment to the dialysis practitioner. Patient months with Medicare physician claims that have more than one provider 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 of 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-9/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 numerator. Medicare claims are used for the comorbidity conditions exclusion criteria. The Medicare Provider Files from the CMS Integrated Data Repository (IDR) are used to identify practitioner's group partners.

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)*

Clinician : Group/Practice, Clinician : Individual

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

Other

If other: Dialysis Facility

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

2. Validity – See attached Measure Testing Submission Form

PhysLTC_testing_07312020_updated.docx

2.1 For maintenance of endorsement

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.

2.2 For maintenance of endorsement

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.

2.3 For maintenance of endorsement

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.

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

Measure Number (*if previously endorsed*)**:**
Measure Title: Hemodialysis Vascular Access: Practitioner Level Long-term Catheter Rate
Date of Submission: **8/3/2020**
Type of Measure:

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

*cell intentionally left blank

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: IDR Medicare Provider table selected for MCPs	☒ other: IDR Medicare Provider table selected for MCPs

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 October 2015 -December 2016 and Medicare claims data from January 2016 – December 2016.

1.3. What are the dates of the data used in testing? January 2016 – December 2016

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:	☐ other:

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 either home or in-center hemodialysis during the last HD treatment of the month from January 2016-December 2016 were included in the analyses. The number of clinicians per month ranged from 7,921-8,058 and the total number of patient-months ranged from 249,965- 256,693.

The number of practitioner groups per month ranged from 8,756-8,904.

Public reporting of this measure on DFC or in the ESRD QIP would be restricted to practitioners or practitioner-groups 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.

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 3,035,130 eligible patient-months. Among those patient-months over the whole year, the average age was 63.6 years, 43.8% of patient-months were female, 56.0% were white, 37.4% were black, 6.5% reported race as "other", 16.2% were Hispanic and 45.8% 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.

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 2016 – December 2016 CROWNWeb data to calculate practitioner -level annual performance scores. The NQF-recommended approach for determining measure reliability is a one-way analysis of variance (ANOVA), in which the between-practitioner variation (σ_b^2) and the within-practitioner 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-practitioner variation, the true signal reflecting the differences across practitioners. We assessed reliability by calculating inter-unit reliability (IUR) for the annual performance scores. If the measure were a simple average across individuals under the care of one practitioner, 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 practitioner variation that cannot be directly estimated by ANOVA. A small IUR (near 0) reveals that most of the variation of the measures between practitioners is driven by random noise, indicating the measure would not be a good characterization of the differences among practitioners, whereas a large IUR (near 1) indicates that most of the variation between practitioners is due to the real difference between practitioners.

Here we describe our approach to calculating IUR. Let T1,…,TN be the annual catheter rate for N practitioners. 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 practitioner, we calculate an annual catheter rate ($T_{i,1}^*$,…, $T_{i,B}^*$) and their sample variance (Si*). From this it can be seen that

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

is a bootstrap estimate of the within-practitioner variance in the catheter rate, where ni is the number of subjects in the ith practitioner. Calling on formulas from the one-way ANOVA, the total variation in the annual catheter rate (i.e., $\sigma_b^2 + \sigma_{t,w}^2$) 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 $\bar{T} = \Sigma \text{ ni Ti} / \Sigma \text{ ni},$, and

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

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

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

To assess more directly the value of this measure in identifying practitioners or group practices with extreme outcomes, we also computed an additional metric of reliability, termed the profile IUR (PIUR) [1]. The PIUR was developed since the IUR can be quite small if there are many providers which have outcomes similar to

the national norm, even though the measure is still very useful to identify providers with extreme outcomes [2]. The PIUR is based on the measure's ability to consistently flag the same provider. We proceed in two steps: first, we evaluate the ability of a measure to consistently profile providers with extreme outcomes; second, we use the IUR to calibrate PIUR. Specifically, we consider a sample-splitting approach: within each provider randomly split patients into two equal-sized subgroups. For a given threshold (e.g. p-value or z-score in a hypothesis testing procedure), determine whether each provider is identified as extreme based on the first and the second subgroups. Repeat this process 100 times to estimate the probability that, given a provider is classified as extreme based on the first subgroup, it is also classified as extreme based on the second subgroup. This empirical reflagging rate is calibrated to give the PIUR by determining the IUR value that would yield this reflagging rate in the absence of outliers. The PIUR measures reliability in terms of the probability of reflagging rates but is on the same scale as IUR. The PIUR is substantially larger than the IUR when the data include many outliers or extreme values that are not captured in the IUR itself.

1. He K, Dahlerus C, Xia L, Li Y, Kalbfleisch JD. The profile inter-unit reliability. Biometrics. 2019 Oct 23. doi: 10.1111/biom.13167. [Epub ahead of print]

2. Kalbfleisch JD, He K, Xia L, Li Y. Does the inter-unit reliability (IUR) measure reliability?, Health Services and Outcomes Research Methodology, 2018 Sept. 18(3), 215-225. Doi: 10.1007/s10742-018-0185-4.

3. He K, Kalbfleisch JD, Yang Y, Fei Z. Inter-unit reliability for nonlinear models. Stat Med. 2019 Feb 28;38(5):844-854. doi: 10.1002/sim.8005. Epub 2018 Oct 18.

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 at practitioner level is 0.602. The PIUR at the practitioner level is 0.804.

The IUR at practitioner group level is 0.793. The PIUR at the practitioner group level is 0.815.

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 IUR at practitioner level indicates that 60.2% of the variation in the annual long-term catheter rate can be attributed to between-practitioner differences in performance (signal) and 39.8% to the within-practitioner variation (noise). This value of IUR implies a moderate degree of reliability. The higher PIUR compared to the IUR indicates the presence of outliers or heavier tails among the providers, which is not captured in the IUR itself. If there are no outliers, one should expect the PIUR to be similar to the IUR; but in cases where there are outlier providers, even measures with a low IUR can have relatively high PIUR and can be very useful for identifying extreme providers.

The IUR at practitioner group level indicates that 79.2% of the variation in the annual long-term catheter rate can be attributed to between-group differences in performance (signal) and 20.7% to the within-group variation (noise). This value of IUR implies 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 the trend test to measure the association between practitioner level long-term catheter rates occurring in January-December 2016 and hospitalization and mortality in the following 12 months. Average mortality rates and prevalence of all-cause hospitalization were calculated in each category of practitioner level catheter rates (i.e. physicians having long-term catheter rates in the lowest 10%, middle, and highest 10% categories respectively).

A similar validity analysis was performed for the practitioner group level long-term catheter rates.

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

Practitioner Level

Mortality rates are 17.0, 18.4 and 20.8 (per 100 patient-years) for practitioners having long-term catheter rates falling into the lowest 10%, middle, and highest 10% categories respectively ($p<0.001$).

Percentages of patient hospitalization (all-cause) are 60.8%, 62.8% and 67.8% for practitioners having long-term catheter rates falling into the lowest 10%, middle, and highest 10% categories respectively ($p<0.001$).

Practitioner Group Level

Mortality rates are 18.4, 18.3 and 21.3 (per 100 patient-years) for practitioner-groups having long-term catheter rates falling into the lowest 10%, middle, and highest 10% categories respectively ($p<0.001$).

Percentages of patient hospitalization (all-cause) are 61.9%, 62.9% and 67.6% for practitioner-groups having long-term catheter rates falling into the lowest 10%, middle, and highest 10% categories respectively ($p<0.001$).

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?*)

Result of the trend test for the lowest 10% and highest 10% categories (reference is the middle 80% category) suggests higher long-term catheter use is associated with both higher all-cause hospitalization and mortality at both the practitioner level and the practitioner group level.

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 practitioner-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. 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*)

Table 1: Percent of patient-months at risk excluded

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

Table 2: Number and percent of unique patients excluded

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

Table 3a: Distribution of performance scores before and after the exclusion, practitioner level

Practitioner-level Catheter Rate	N	Mean	Standard Deviation	Minimum	Maximum
Before exclusion	8037	10.4%	6.5%	0.0%	66.2%

Practitioner-level Catheter Rate	N	Mean	Standard Deviation	Minimum	Maximum
After exclusion	8037	9.7%	6.3%	0.0%	66.2%

Table 3b: Distribution of performance scores before and after the exclusion, practitioner-group level

Practitioner group-level Catheter Rate	N	Mean	Standard Deviation	Minimum	Maximum
Before exclusion	8649	8.3%	6.3%	0.0%	46.9%
After exclusion	8649	7.8%	6.0%	0.0%	46.9%

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

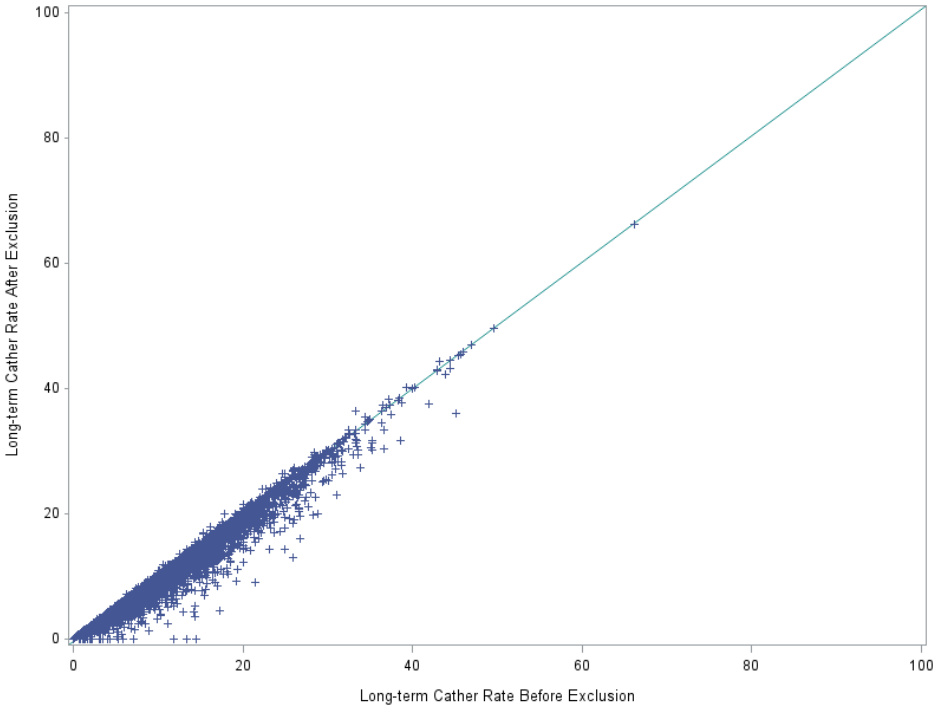

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Figure 2. Distribution of Excluded Patients at the practitioner level for 2016

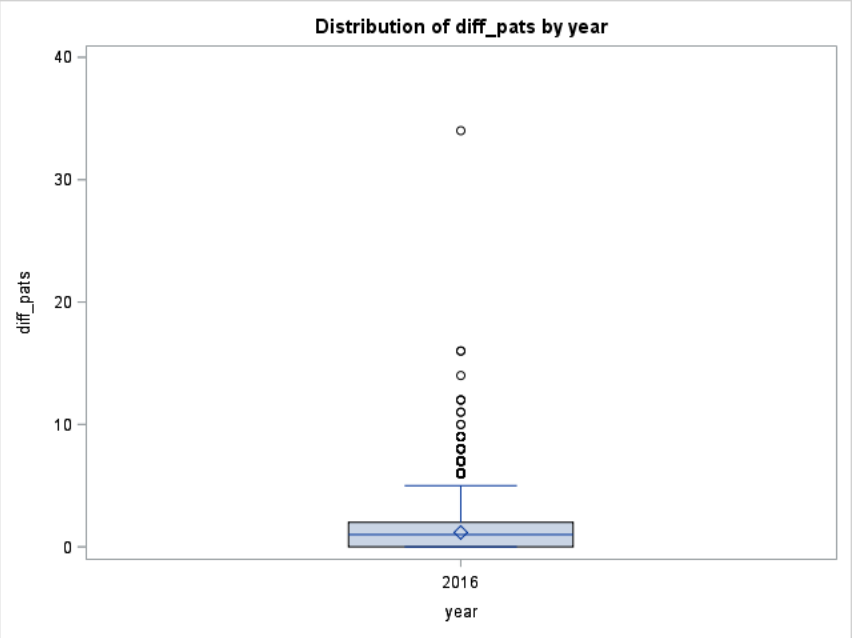


Figure 3: Scatterplot – Practitioner Group Catheter Rate with and without Exclusions

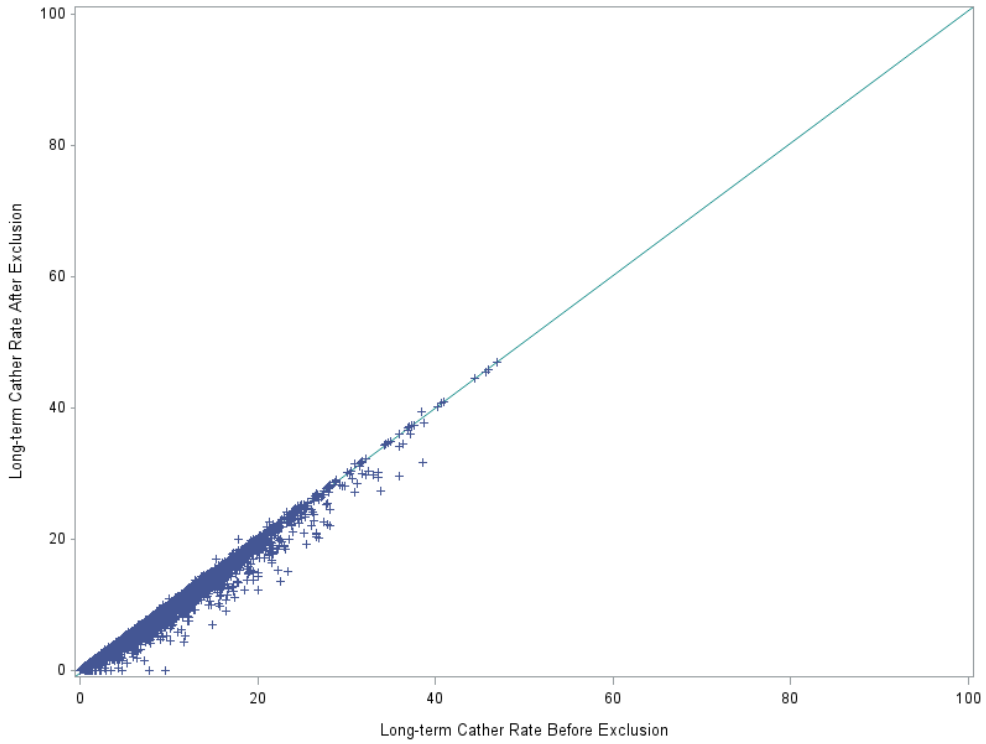
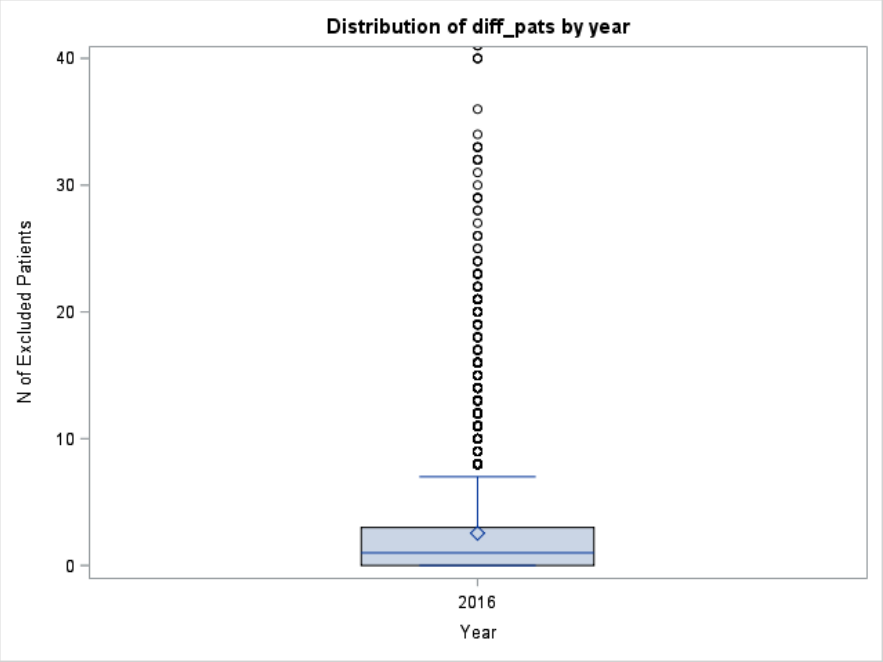


Figure 4. Distribution of Excluded Patients at the practitioner group level for 2016



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*)

Practitioner level

The exclusion criteria are necessary since the percentage of patients excluded with each practitioner is not evenly distributed across practitioners (Distribution shown in the boxplot). Due to the unequal distribution across practitioners, the exclusion criteria take into account that some practitioners 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 0.982 (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.

Practitioner-group level

The exclusion criteria are necessary since the percentage of patients excluded with each practitioner group is not evenly distributed across practitioner groups (Distribution shown in Figure 4). Due to the unequal distribution across practitioner groups, the exclusion criteria take into account that some groups treat a higher portion of patients with limited life expectancy. Additionally, our results shown in both the scatter-plot (Figure 3) as well as the Pearson Correlation Coefficient of 0.990 (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.

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 risk factors**

☐ **Stratification by risk categories**

☐ **Other,**

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. A facility-level version of this measure was reviewed by the 2015 vascular access TEP which also did not recommend risk adjustment. That TEP report can be found here:https://dialysisdata.org/sites/default/files/content/ESRD_Measures/ESRD_Vascular_Access_TEP_Summary_Report.pdf

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. These same reasons apply to the practitioner level catheter measure. In order to optimally harmonize this practitioner level measure with the dialysis facility measure previously reviewed by NQF, we have not provided risk adjustment, beyond the previously noted exclusion criteria.

Data used to support our rationale for no risk adjustment for this measure are included in Section 1b.4 of the Measure Information Form, and have been included below (in italics). 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 would weaken the intended disincentive to catheter use. Furthermore, demographic and comorbidity factors that are important in vascular access creation and would be considered as potential risk adjusters, such as age and diabetes, are particularly relevant for AV *fistula* creation. Older patients or those with multiple comorbidities are generally candidates for creation of an AV graft, which is, in the absence of very limited life expectancy (see Exclusions), considered a much better alternative to a long-term catheter. Applying the exclusions more appropriately accounts for conditions in a very specific subset of patients where a catheter is the most clinically appropriate access type.

Using the data from Jan-Dec 2016, age, sex, race, ethnicity and dialysis vintage were evaluated in a logistic regression model for long-term catheter use. Below we report the odds ratios for these patient characteristics. Age, sex, race, ethnicity and dialysis vintage are all statistically significant predictors of long-term catheter use. The analysis results indicate potential disparity in prolonged use of a tunneled catheter among these groups. Specifically, females are about 33% more likely to have a long-term catheter as males. Individuals 75 years of age and older were 13% more likely to have a long-term catheter and younger individuals 18-25 years of age were 43% more likely to have a long-term catheter when compared to patients 60-75 years of age. Those whose race is reported as "Other" were less likely to have a long-term catheter when compared to whites, as were Hispanics, when compared to non-Hispanics. In the absence of biological effects explaining these differences, risk adjustment for these demographic factors could potentially mask disparities in care.

Odds ratio of having a catheter for at least three months:

Age:

- *For the 18-<25 age group, the Odds Ratio is 1.43, P-value is <. 0001.*
- *For the 25-<59 age group, the Odds Ratio is 1.08, P-value is <.0001.*
- *The 60-<75 age group was used as the reference group.*
- *For the 75+ age group, the Odds Ratio is 1.13, P-value is <.0001.*

Sex:

- *For Female: The Odds Ratio is 1.33, and the P-value is <.0001.*
- *Male was used as the reference group.*

Race:

- *White was used as the reference group.*
- *For Black: The Odds Ratio is 0.88, and the P-value is <.0001.*
- *For Other: The Odds Ratio is 0.92, and the P-value is <.0001.*

Ethnicity:

- *For Hispanic: The Odds Ratio is 0.76, and the P-value is <.0001.*
- *Non-Hispanic was used as the reference group.*

Employment Status:

- *Employed was used as the reference group.*
- *For Unemployed: The Odds Ratio is 1.22, and the P-value is <.0001.*
- *For Other: The Odds Ratio is 1.40, and the P-value is <.0001.*

Medicare Coverage:

- *Medicare as primary w/o Medicaid was used as the reference group.*
- *Medicare as primary with Medicaid: The Odds Ratio is 1.08, and the P-value is <.0001.*
- *Medicare as secondary/Medicare HMO: The Odds Ratio is 0.82, and the P-value is <.0001.*
- *For Non-Medicare/missing: The Odds Ratio is 0.76, and the P-value is <.0001.*

ADI (zipcode-level):

- *Unemployment rate (%): The Odds Ratio is 1.00, and the P-value is 0.07.*
- *Median family income: The Odds Ratio is 0.99, and the P-value is 0.28.*
- *Families below the poverty level (%): The Odds Ratio is 1.01, and the P-value is 0.09.*
- *Single-parent households with children <18 (%): The Odds Ratio is 0.996, and the P-value is <.0001.*
- *Home ownership rate (%): The Odds Ratio is 0.997, and the P-value is <.0001.*
- *Median home value: The Odds Ratio is 0.99, and the P-value is 0.26.*
- *Median monthly mortgage: The Odds Ratio is 1.07, and the P-value is 0.02.*
- *Median gross rent: The Odds Ratio is 1.05, and the P-value is 0.20.*
- *Population (aged 25+) without High School diploma (%): The Odds Ratio is 1.00, and the P-value is 0.69.*
- *Income disparity: The Odds Ratio is 1.01, and the P-value is 0.09.*

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 practitioner or practitioner group using patient level analyses. For each practitioner/practitioner group, 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 with the practitioner/practitioner group, 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 with each practitioner/practitioner group 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 with each practitioner will follow the overall national distribution.

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 4a: Proportion of practitioners with statistically significant differences (p-value < 0.025) is shown as follows:

Category	Number of practitioners	Percent of practitioners
As expected	7,236	91.1
Worse than expected	708	8.9

Table 4b: Proportion of practitioner groups with statistically significant differences (p-value < 0.025) is shown as follows:

Category	Number of practitioner groups	Percent of practitioner groups
As expected	7,729	89.4
Worse than expected	920	10.6

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 practitioner level percentage of patients with a long-term catheter as the performance measure, 7,236 (91.1%) practitioners have achieved expected performance, and 708 (8.9%) practitioners have performed worse than expected (higher catheter rate). For the annual practitioner group level percentage of patients with a long-term catheter as the performance measure, 7,661 (89.4%) practitioner groups have achieved expected performance, and 913 (10.6%) practitioner groups 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 practitioners/practitioner groups 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 non-responders) 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 Long-term Catheter measure is based on data from CROWNWeb (representative of all ESRD dialysis patients) and Medicare claims. The source of vascular access type is CROWNWeb and while missing data for vascular access type occurs only rarely, reporting months with missing values are not excluded from this measure. We report the frequency of the overall percentage of patient months with missing vascular access type.

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	54659	1.80
No	2541698	83.74
Yes	438774	14.46

We were unable to determine the presence of comorbidities for the limited life expectancy exclusion conditions in 1.83% 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 non-responders) 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 1.83% 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).

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.

N/A

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 Payment Program	*

*cell intentionally left blank

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

N/A

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?*)

The measure is currently undergoing initial endorsement review.

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.*)

Upon completion of endorsement review, CMS will consider this measure for implementation in public reporting for such programs as Medicare Care Compare and/or the Quality Payment Program. If required by the program, the measure will be submitted to the NQF Measures Application Partnership for review prior to implementation.

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.

N/A

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.

N/A

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.

N/A

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

N/A

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

N/A

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.

N/A

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.

The measure is not yet implemented in a public reporting program, so improvement could not be evaluated. CMS currently anticipates implementation of this catheter measure. Once implemented practitioner performance on the measure can be evaluated to determine if the measure has supported and detected quality improvement in reducing prolonged catheter use, while accounting for patients where a long-term catheter may be an appropriate vascular access choice.

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.

N/A

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

N/A

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)

2977 : Hemodialysis Vascular Access: Standardized Fistula Rate

2978 : Hemodialysis Vascular Access: Long-term Catheter Rate

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?

Yes

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

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.)

N/A

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: PhysLTC_FlowChart.pdf

Contact Information

Co.1 Measure Steward (Intellectual Property Owner): Centers for Medicare & Medicaid Services

Co.2 Point of Contact: Helen, Dollar-Maples, Helen.Dollar-Maples@cms.hhs.gov, 410-786-7214-

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

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.

Measure Developer/Steward Updates and Ongoing Maintenance

Ad.2 Year the measure was first released: 2020

Ad.3 Month and Year of most recent revision:

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

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

Ad.6 Copyright statement:

Ad.7 Disclaimers:

Ad.8 Additional Information/Comments: