



Measure Information

This document contains the information submitted by measure developers/stewards, but is organized according to NQF's measure evaluation criteria and process. The item numbers refer to those in the submission form but may be in a slightly different order here. In general, the item numbers also reference the related criteria (e.g., item 1b.1 relates to sub criterion 1b).

Brief Measure Information

NQF #: 2977

Corresponding Measures:

De.2. Measure Title: Hemodialysis Vascular Access: Standardized Fistula Rate

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

De.3. Brief Description of Measure: Adjusted percentage of adult hemodialysis patient-months using an autogenous arteriovenous fistula (AVF) as the sole means of vascular access.

1b.1. Developer Rationale: The NKF K/DOQI guidelines state the following: 1) AV fistulas have the lowest rate of thrombosis and require the fewest interventions, 2) cost of AV fistula use and maintenance is the lowest, 3) fistulas have the lowest rates of infection, and 4) fistulas are associated with the highest survival and lowest hospitalization rates. Indeed, a number of epidemiologic studies consistently demonstrate the reduced morbidity and mortality associated with greater use of AV fistulas for vascular access in maintenance hemodialysis.

As the accompanying literature review indicates, there are a growing number of studies reporting that creating AVF in some patients is less likely to be successful in the presence of certain comorbidities. In addition, certain patient groups may have less incremental benefit from an AV fistula relative to an AV graft. By adjusting the fistula rate for patient characteristics and comorbidities associated with low AV fistula success rates, this measure accounts for patients where a graft or even a catheter may be a more appropriate option.

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

S.4. Numerator Statement: The numerator is the adjusted count of adult patient-months using an AVF as the sole means of vascular access as of the last hemodialysis treatment session of the month.

S.6. Denominator Statement: All patient-months for 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 entire reporting month at the same facility.

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

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

- Pediatric patients (<18 years old)
- Patients on Peritoneal Dialysis
- Patient-months with in-center or home hemodialysis for less than a complete reporting month at the same facility

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

Patients with a catheter that have limited life expectancy:

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

• Patients with coma or anoxic brain injury in the past 12 months
De.1. Measure Type: Outcome: Intermediate Clinical Outcome S.17. Data Source: Claims, Registry Data S.20. Level of Analysis: Facility
IF Endorsement Maintenance – Original Endorsement Date: Dec 09, 2016 Most Recent Endorsement Date: Dec 09, 2016
IF this measure is included in a composite, NQF Composite#/title: IF this measure is paired/grouped, NQF#/title: De.4. IF PAIRED/GROUPED, what is the reason this measure must be reported with other measures to appropriately interpret results? N/A

1. Evidence, Performance Gap, Priority – 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 2977_Evidence_Form-637213760759543328.docx 1a.1 For Maintenance of Endorsement: Is there new evidence about the measure since the last update/submission? Do not remove any existing information. If there have been any changes to evidence, the Committee will consider the new evidence. Please use the most current version of the evidence attachment (v7.1). Please use red font to indicate updated evidence. Yes
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) <i>If a COMPOSITE (e.g., combination of component measure scores, all-or-none, any-or-none), SKIP this question and answer the composite questions.</i> The NKF K/DOQI guidelines state the following: 1) AV fistulas have the lowest rate of thrombosis and require the fewest interventions, 2) cost of AV fistula use and maintenance is the lowest, 3) fistulas have the lowest rates of infection, and 4) fistulas are associated with the highest survival and lowest hospitalization rates. Indeed, a number of epidemiologic studies consistently demonstrate the reduced morbidity and mortality associated with greater use of AV fistulas for vascular access in maintenance hemodialysis. As the accompanying literature review indicates, there are a growing number of studies reporting that creating AVF in some patients is less likely to be successful in the presence of certain comorbidities. In addition, certain patient groups may have less incremental benefit from an AV fistula relative to an AV graft. By adjusting the fistula rate for patient characteristics and comorbidities associated with low AV fistula success rates, this measure accounts for patients where a graft or even a catheter may be a more appropriate option. This measure is intended to be jointly reported with Hemodialysis Vascular Access: Long-term Catheter Rate. These two vascular access quality measures, when used together, consider Arterial Venous Fistula (AVF) use as a positive outcome and prolonged use of a tunneled catheter as a negative outcome. With the growing recognition that some patients have exhausted options for an AVF or have comorbidities that may limit the success of AVF creation, joint reporting of the measures accounts for all three vascular access options. The fistula measure adjusts for patient factors where fistula placement may be either more difficult or not appropriate and acknowledges that in certain circumstances an AV graft may be the best access option. This paired incentive structure that relies on both measures (SFR, long-term catheter rate) reflects consensus best practice, and supports maintenance of the gains in vascular access success achieved via the Fistula First/Catheter Last Project over the last decade.

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.*

The newly revised NKF K/DOQI guidelines indicate that an arteriovenous access is preferable to a long-term catheter in most incident and prevalent hemodialysis patients. Furthermore, if patient circumstances are favorable, an AV fistula is preferable to an AV graft in incident dialysis patients due to fewer long-term vascular access events such as thrombosis and need for interventions. Although prior KDOQI guidelines indicated that AV fistula were associated with improved outcomes (improved patency, lower cost, lower complications) relative to AV grafts or long-term catheters, concern has been raised about significant bias in the older literature on which these conclusions had been made. Still, recent studies consistently find that AV fistula have the lowest rates of infection, and are associated with the highest survival of the three access types. Over the period from 2005-2016, the percentage of patients initiating hemodialysis with an AV fistula increased from 12% to 17%. By the middle of 2017 62.8% of prevalent hemodialysis patients were dialyzing with an AV fistula (USRDS 2018).

As the accompanying literature review indicates (see Evidence form), there are a growing number of studies reporting that creating AVF in some patients is less likely to be successful in the presence of certain comorbidities. In addition, certain patient groups may have less incremental benefit from an AV fistula relative to an AV graft. By adjusting the fistula rate for patient characteristics and comorbidities associated with low AV fistula success rates, this measure accounts for patients where a graft or even a catheter may be a more appropriate option. This approach is supported by the recent KDOQI updated guidelines which stress a patient centered approach to vascular access.

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

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

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.

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

Older age, sex, race, and ethnicity are all statistically significant predictors of AVF use. Specifically, patients 75 years of age or older had 15% lower odds of having an AV fistula when compared to the younger reference group while females had about a 44% lower odds of having a fistula versus males. Hispanic ethnicity was associated with higher odds of fistula use whereas blacks had about a 31% lower odds of fistula use compared to whites. Unemployment or "other" employment status, as well as dual eligible status

were all associated with lower odds of fistula use. The analysis results for age, race, sex and patient SES indicate potential disparities in fistula use. Patient-level SDS/SES variables are not included as adjustments in the measure due to the absence of a convincing biological or clinical rationale that warrant accounting for different outcomes on the basis of race, sex, or socioeconomic status. Adjusting for these factors could have the unintended effect of masking or reinforcing disparities in vascular access outcomes (see Section 2b3.4b in the Testing form).

Odds ratio of having a fistula:

Age:

For the 18-<25 age group, the Odds Ratio (95% CI) is 0.91 (0.72, 1.15), P-value is 0.415.

For the 25-<60 age group, the Odds Ratio (95% CI) is 1.03 (0.98, 1.07), P-value is 0.220.

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

For the 75+ age group, the Odds Ratio (95% CI) is 0.85 (0.81, 0.90), P-value is <0.001.

Sex:

For Female: the Odds Ratio (95% CI) is 0.56 (0.54, 0.58), P-value is <0.001.

Male was used as the reference group.

Race:

White was used as the reference group.

For Black: the Odds Ratio (95% CI) is 0.69 (0.66, 0.73), P-value is <0.001.

For Other race: the Odds Ratio (95% CI) is 1.04 (0.95, 1.14), P-value is 0.347.

Ethnicity:

For Hispanic: the Odds Ratio (95% CI) is 1.24 (1.16, 1.32), P-value is <0.001.

Non-Hispanic was used as the reference group.

Employment Status:

Employed was used as the reference group.

For Unemployed: The Odds Ratio (95% CI) is 0.83 (0.78, 0.88), and the P-value is <0.001.

For Other: The Odds Ratio (95% CI) is 0.78 (0.74, 0.83), and the P-value is <0.001.

Medicare Coverage:

Dual eligibility: the Odds Ratio (95% CI) is 0.94 (0.90, 0.98), and the P-value is 0.003.

Non-Dual eligibility was used as the reference group.

ADI (zipcode-level):

National percentile ADI score: The Odds Ratio (95% CI) is 1.00 (1.00, 1.00), and the P-value is 0.512.

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

N/A

2. Reliability and Validity—Scientific Acceptability of Measure Properties

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

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

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

Renal, Renal : End Stage Renal Disease (ESRD)

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

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

Populations at Risk

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

N/A

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

This is not an eMeasure Attachment:

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

Attachment Attachment: 2977_Data_Dictionary_Code_Table.xlsx

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

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

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

Not an instrument-based measure

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

Yes

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.

Refinements have been made to the specifications and risk adjustment model. Specifically, we modified the following:

- Revised the BMI categories to correspond with WHO classifications; assign patients with missing BMI to obese category.
- Added a binary Medicare coverage indicator: Patient-months where patient had at least 6 Medicare covered months OR 1 Medicare Advantage covered month or more in the past 12 months. This indicator is used to determine the presence of prevalent comorbidities from Medicare claims, in the prior year.
- Added a binary missing indicator to account for patients without a ME 2728 form. This helps control for patients that may have incident comorbidities but because we do not have a 2728 we cannot observe these.
- Revised the nursing home indicator to distinguish between long and short-term nursing home stays in the prior 12 months. The more granular indicators for length of stay more directly account for the impact of longer term nursing home stays which generally reflect a sicker population.

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 adjusted count of adult patient-months using an AVF as the sole means of vascular access as of the last hemodialysis treatment session of the 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).

The number of patient-months using an AVF as the sole means of vascular access at a given facility, adjusted for patient-mix. An AVF is considered in use if the CROWNWeb “Access Type IDs” of 14 or 22 has been recorded for a given month, where “14” represents AV fistula only (with 2 needles) and “22” represents AV fistula only with an approved single needle device.

Patients with a missing vascular access type are counted in the denominator, but not the numerator. For comorbidities, if the patient had missing comorbidity values both in the preceding 12 months of Medicare claims and in the Medical Evidence Form for the corresponding comorbidity, we assume this patient did not have the comorbidity in that reporting month. The same methodology is applied to the comorbidity exclusions and the hospice exclusion.

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

All patient-months for 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 entire reporting month at the same facility.

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

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

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

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

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

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

Exclusions that are implicit in the denominator definition include:

- Pediatric patients (<18 years old)
- Patients on Peritoneal Dialysis
- Patient-months with in-center or home hemodialysis for less than a complete reporting month at the same facility

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

Patients with a catheter that have limited life expectancy:

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

S.9. Denominator Exclusion Details *(All information required to identify and calculate exclusions from the denominator such as*

definitions, time period for data collection, specific data collection items/responses, code/value sets – Note: lists of individual codes with descriptors that exceed 1 page should be provided in an Excel or csv file in required format at S.2b.)

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

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

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

Hospice status is determined from a separate CMS file that contains final action claims submitted by Hospice providers. Once a beneficiary elects Hospice, all Hospice related claims will be found in this file, regardless if the beneficiary is in Medicare fee-for-service or in a Medicare managed care plan. Patients are identified as receiving hospice care if they have any final action claims submitted to Medicare by hospice providers in the current month.

Diagnoses of metastatic cancer, end stage liver disease, or coma in the past 12 months were determined from Medicare claims. Medicare claim types include inpatient admissions, outpatient claims (including dialysis claims) and physician services. Claims from providers, such as laboratories that report diagnosis codes when testing for the presence of a condition are excluded. A detailed list of ICD-10 diagnostic codes used to identify these comorbidities is included in the attached data dictionary code table (excel file).

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)

Statistical risk model

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 = Higher 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 the Renal Management Information System (REMIS), 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 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. Past-year comorbidity data are obtained from multiple Part A types (inpatient, home health, hospice, skilled nursing facility claims) and Part B (outpatient) claims.

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

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

No data collection instrument provided

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

Facility

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

Other

If other: Dialysis Facility

S.22. 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.*)

N/A

2. Validity – See attached Measure Testing Submission Form

[2977_Testing_form.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.

Yes

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.

Yes

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.

Yes - Updated information is included

3. Feasibility

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

3a. Byproduct of Care Processes

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

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

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

If other:

3b. Electronic Sources

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

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

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

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

N/A

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

Attachment:

3c. Data Collection Strategy

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

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

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

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

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

N/A

4. Usability and Use

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

4a. Accountability and Transparency

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

4.1. Current and Planned Use

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

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

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

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

DFC:

Purpose: Dialysis Facility Compare helps patients find detailed information about Medicare-certified dialysis facilities. They can compare the services and the quality of care that facilities provide.

Geographic area: United States

Number of accountable entities: All Medicare-certified dialysis facilities that are eligible for the measure, and have at least 11 patients in the reporting month. For the most recent update to Dialysis Facility Compare (January 2020), 6916 facilities had a score reported.

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

QIP:

Purpose: The ESRD QIP will reduce payments to ESRD facilities that do not meet or exceed certain performance standards. The measure was added to the program for PY2021

Geographic area: United States

Number of accountable entities: All Medicare-certified dialysis facilities that are eligible for the measure, and have at least 11 patients in the reporting month. The measure will first appear in the ESRD QIP for PY 2021 (released July 2020)

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

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

N/A

4a1.3. If not currently publicly reported OR used in at least one other accountability application, provide a credible plan for

implementation within the expected timeframes -- any accountability application within 3 years and publicly reported within 6 years of initial endorsement. *(Credible plan includes the specific program, purpose, intended audience, and timeline for implementing the measure within the specified timeframes. A plan for accountability applications addresses mechanisms for data aggregation and reporting.)*

N/A

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

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

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

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

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

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

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

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

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

Describe how feedback was obtained.

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

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

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

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

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

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

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

Comments were also received on additional clinical risk adjustors and exclusions, including exhausting all other vascular access options.

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.

As described in S.3.2, the measure has been updated and refined for this maintenance review, but we did not make changes that directly address the feedback described in 4a2.2.3. In response to feedback that the measure should account for patient choice in selecting a vascular access, we acknowledge that it is important that patient preference is taken into account in treatment plans and a patient's "ESKD life plan", as referenced in the updated 2019 KDOQI vascular access guidelines. Patient choice or preference is ostensibly a patient reported outcome however at this time there are no standard criteria for how to validate informed choice, such as a patient's preference to have a catheter (or arteriovenous graft) versus an AV fistula. Check-boxes indicating "received educational materials" or attested to selecting their preferred access type may not be sufficient for determining whether an informed and express choice was made by the patient. Doing so would require ascertaining and measuring 1) what constitutes adequate vascular access education by a nephrologist from the patient's perspective and 2) how that in turn resulted in an informed choice. Accurately capturing informed patient choice may be a particular concern for vulnerable patients.

In response to concerns about facilities potentially being doubly penalized by the fistula and catheter vascular access measures, we explain that when used together, AV fistula is considered a positive outcome and prolonged use of a tunneled catheter as a negative outcome, while graft use is neutral and does not count against a facility. With the growing recognition that some patients have exhausted options for an arteriovenous fistula, or have comorbidities that may limit the success of AV fistula creation, pairing the measures accounts for all three vascular access options. This paired incentive structure that relies on both measures reflects consensus best practice, and supports maintenance of the gains in vascular access success achieved via the Fistula First/Catheter Last Project and the ESRD Networks over the last decade. Additionally, the standardized fistula rate measure includes risk adjustment for patient clinical factors where fistula placement may be either more difficult or not appropriate and acknowledges that in certain circumstances an AV graft may be the best access option. Both the fistula and catheter measures apply exclusions for certain conditions recognizing that catheter placement may be the only means of vascular access for these patient sub-populations. Specifically, both measures exclude patients with a catheter that have limited life expectancy defined as being under hospice care in the current reporting month, or a diagnosis with metastatic cancer, end stage liver disease, coma or anoxic brain injury in the past 12 months. In this way, the combination of risk adjustment for the standardized fistula rate measure and the application of the exclusions to both measures does not result in doubly penalizing facilities and instead is intended to incentivize best practices for vascular access.

In response to comments about expanding the exclusion criteria, many of the comorbidity based exclusions suggested by commenters are either associated with shortened life expectancy or low likelihood of successful fistula placement. Specific conditions associated with limited life expectancy are already part of the exclusion criteria for both measures. Disease severity for many conditions, such as heart failure, is difficult to ascertain from claims data and did not improve significantly with the change from ICD-9 to ICD-10 codes. Other comorbidities will continue to be evaluated in future measure maintenance. Lastly, multiple prior failed vascular access attempts were considered by the TEP as an exclusion criterion to address the exhaustion of vascular sites or failed attempts to create a fistula or graft, however consensus was not reached by the TEP on how best to implement this exclusion. At the present time, historical vascular access data in CROWNWeb do not have enough reliability to be used as part of an exclusion criteria. This will also be re-evaluated with future updates as part of the measure maintenance process.

Improvement

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

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

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

Q1 2018: N of Facilities = 6711, Mean % = 62.16, Std Dev = 14.08, Min % = 0, Max % = 100

Q2 2018: N of Facilities = 6779, Mean % = 62.32, Std Dev = 13.62, Min % = 0, Max % = 100

Q3 2018: N of Facilities = 6816, Mean % = 62.97, Std Dev = 12.41, Min % = 0, Max % = 100

Q4 2018: N of Facilities = 6828, Mean % = 63.06, Std Dev = 12.13, Min % = 0, Max % = 100

The percentage of facility level fistula rates increased from quarter 1 to quarter 4 for 2018, suggesting improvement in national facility level fistula rates over the period.

4b2. Unintended Consequences

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

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

None

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

None

5. Comparison to Related or Competing Measures

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

5. Relation to Other NQF-endorsed Measures

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

Yes

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

2594 : Optimal End Stage Renal Disease (ESRD) Starts

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

5a. Harmonization of Related Measures

The measure specifications are harmonized with related measures;

OR

The differences in specifications are justified

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

Are the measure specifications harmonized to the extent possible?

No

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

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

5b. Competing Measures

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

OR

Multiple measures are justified.

5b.1. If this measure conceptually addresses both the same measure focus and the same target population as NQF-endorsed measure(s):
Describe why this measure is superior to competing measures (e.g., a more valid or efficient way to measure quality); OR provide a rationale for the additive value of endorsing an additional measure. (Provide analyses when possible.)
[There are no competing measures.](#)

Appendix

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

[Attachment](#) **Attachment:** [2977_Flow_Chart.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, 734-936-5711-

Additional Information

Ad.1 Workgroup/Expert Panel involved in measure development

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

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

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Measure Developer/Steward Updates and Ongoing Maintenance

Ad.2 Year the measure was first released: 2016

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

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

Ad.5 When is the next scheduled review/update for this measure? 04, 2021

Ad.6 Copyright statement:

Ad.7 Disclaimers:

Ad.8 Additional Information/Comments: