NATIONAL QUALITY FORUM
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Memo

November 17, 2020

To: Consensus Standards Approval Committee (CSAC)

From: Renal Project Team

Re: Renal Spring 2020 Measures[a]

CSAC Action Required

The CSAC will review recommendations from the Renal project at its November 17-18, 2020 meetings and vote on whether to uphold the recommendations from the Committee.

This memo includes a summary of the project, measure recommendations, themes identified and responses to the public and member comments and the results from the NQF member expression of support. The following documents accompany this memo:

1. **Renal Spring 2020 Draft Report**. The draft report has been updated to reflect the changes made following the Standing Committee's discussion of public and member comments. The complete draft report and supplemental materials are available on the project webpage.
2. **Comment Table**. Staff has identified themes within the comments received. This table lists nine comments received during the post-meeting comment period and the NQF/Standing Committee responses.

NQF will provide an informational update to the CSAC on the Renal project at its November 17-18, 2020 meeting.

This memo includes a summary of the project, and themes identified and responses to the public and member comments. Accompanying this memo is the draft report, which is available on the project webpage.

Background

Renal disease is a leading cause of morbidity and mortality in the United States. More than 36 million adults (14 percent of the adult population) have chronic kidney disease (CKD).[1] Untreated, CKD can progress to an advanced state of kidney dysfunction known as end-stage renal disease (ESRD) and a host of other health complications such as cardiovascular disease, hyperlipidemia, anemia, and metabolic bone disease. Currently, over half a million people in the U.S. have received a diagnosis of ESRD.[1] Considering the high mortality rates and high healthcare utilization and costs associated with ESRD, the need to focus on quality measures for patients with renal disease is of the highest importance.

[a] This memo is funded by the Centers for Medicare and Medicaid Services under contract HHSM-500-2017-00060I Task Order HHSM-500-T0001.

Quality measurement plays a central role in facilitating improvement in the quality of care received by CKD patients, especially those on hemodialysis (HD). NQF-endorsed kidney care measures are used in several quality and performance improvement programs administered by the Centers for Medicare and Medicaid Services (CMS), such as Dialysis Facility Compare and the ESRD Quality Incentive Program (ESRD QIP).

This project sought to identify and endorse performance measures for accountability and quality improvement that address conditions, treatments, interventions, or procedures relating to kidney disease.

For the spring 2020 measure review cycle, the Standing Committee evaluated three measures undergoing maintenance review against NQF's standard evaluation criteria. The Committee recommended two measures for endorsement, and the Committee did not recommend consensus on one measure. The measures recommended for endorsement are:

- **NQF 0369** Standardized Mortality Ratio for Dialysis Facilities (University of Michigan Kidney Epidemiology and Cost Center (UM-KECC))
- **NQF 2978** Hemodialysis Vascular Access, Long-Term Catheter Rate (UM-KECC)

The measure not recommended for endorsement is:

- **NQF 2977** Hemodialysis Vascular Access, Standardized Fistula Rate (UM-KECC)

Draft Report

The Renal Spring 2020 draft report presents the results of the evaluation of three measures considered under the Consensus Development Process (CDP). Two are recommended for endorsement and one was not recommended.

The measures were evaluated against the 2019 version of the measure evaluation criteria.

	Maintenance	New	Total
Measures under consideration	3	0	3
Measures recommended for endorsement	2	0	2
Measures not recommended for endorsement or trial use	1	0	1
Reasons for not recommending	Importance - 1 Scientific Acceptability - 0 Use - 0 Overall - 0 Competing Measure - 0	Importance - 0 Scientific Acceptability - 0 Use - 0 Overall - 0 Competing Measure – 0	

Pursuant to the CDP, the CSAC is asked to consider endorsement of two candidate consensus measures.

Measures Recommended for Endorsement

- NQF 0369 Standardized Mortality Ratio for Dialysis Facilities (University of Michigan Kidney Epidemiology and Cost Center (UM-KECC))

Overall Suitability for Endorsement: Yes-11; No-4

- NQF 2978 Hemodialysis Vascular Access, Long-Term Catheter Rate (UM-KECC)

Overall Suitability for Endorsement: Yes-16; No-0

Measures Not Recommended for Endorsement

(See Appendix B for the Committee's votes and rationale)

- NQF 2977 Hemodialysis Vascular Access, Standardized Fistula Rate (UM-KECC)

Comments and Their Disposition

NQF received nine comments from four member organizations and individuals pertaining to the draft report.

A table of comments submitted during the comment period, with the responses to each comment and the actions taken by the Committee, is posted to the Renal project webpage.

Comment Themes and Committee Responses

The Committee reviewed all of the submitted comments. Committee members focused their discussion on measures or topic areas with the most significant and recurring issues.

Themed Comments

Theme 1 – Score Level Reliability Methods: IUR and PIUR

One of the measures under consideration utilized interunit reliability (IUR) testing along with an additional analysis of the profile interunit reliability (PIUR). IUR testing is a common score-level reliability test that produces a signal-to-noise analysis. It was noted that PIUR provides a complimentary analysis that shows the measures' ability to detect outliers. The Committee considered whether PIUR is appropriate as a measure of score level reliability analysis since it does not determine if providers are distinguishable one from another. In fact, its best use is in determining the appropriateness of the measure in cases when most providers in a sample do not have a high IUR rating.

> The developer noted that the accountability application determines whether the measure is sufficiently reliable for a given set of providers. For example, if the provider sample is highly clustered around a mean, an incentive (or disincentive) program for providers who perform significantly outside of the mean may be considered reliable, where a program that rewarded providers simply by their ranking may not be reliable because of the clustering of providers. These reflections resulted in the Committee discussing a potential need for NQF to consider specifying the intended use of a given measure and include application as part of endorsement consideration. NQF's use and usability criteria assesses the extent to which potential audiences (e.g., consumers, purchasers, providers, policymakers) 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. NQF's current process grants endorsement and signals the measure is appropriate for use in any accountability application.

Committee Response

The Committee thanks the commenters and measure developer for their clarification and comment.

Theme 2 – Downgrading of Evidence

The Committee considered two measures that were based on updated guidelines from the National Kidney Foundation's (NKF) Kidney Disease Outcomes Quality Initiative (KDOQI). During the most recent update, KDOQI conducted an in-depth review of the evidence base for the recommendations within the guideline, including a systematic review of the literature. This resulted in downgraded evidence that had previously been ranked as high to expert opinion for the measure focus of two measures reviewed for maintenance of endorsement by the Committee this cycle. The measure developer supplemented the systematic review in KDOQI with additional journal articles. Nonetheless, the Committee felt it especially important to carefully consider the implications of the downgrading of evidence for these two measures, ultimately concluding that the evidence to support the use of fistulas was not as strong as the evidence against the use of catheters for vascular access.

Committee Response

The Committee re-voted on evidence for measure 2977. The measure failed on evidence and the committee voted not to recommend measure 2977 for endorsement. This was because the downgrading of evidence in the KDOQI hemodialysis guideline resulted in a reliance on expert opinion as the basis for the measure, which the Committee considers not to meet the NQF standard for evidence.

Theme 3 – Preferred Routes of Vascular Access for Hemodialysis

The Committee noted that the preferred route of vascular access is via an AVF. The Committee expressed that patient preference will be a confounding factor in any measure of vascular access. Moreover, the Committee also noted that there are many instances when an AVF may not be the preferred access route for certain patients, even in the face of known risks. The Committee noted that measurement in this domain could create unintended consequences for patients for whom an AVF may not be the most desirable approach due to downward pressure on clinicians to order them—even where there is a more patient-centered option. The Committee also noted that advancement in its technology (e.g. catheter locks) will create additional need for careful consideration on the part of the measure developer to consider the implications in overall undesirability associated with catheter use.

Committee Response

The Committee thanks the commenters and the measure developer for their clarification and comment.

Member Expression of Support

Throughout the 16-week continuous public commenting period, NQF members had the opportunity to express their support ('support' or 'do not support') for each measure submitted for endorsement consideration to inform the Committee's recommendations. Two NQF members provided their expression of support and one NQF member provided expression of non-support. Appendix C details the expression of support.

Appendix A: CSAC Checklist

The table below lists the key considerations to inform the CSAC's review of the measures submitted for endorsement consideration.

Key Consideration	Yes/No	Notes
Were there any process concerns raised during the CDP project? If so, briefly explain.	No	
Did the Standing Committee receive requests for reconsideration? If so, briefly explain.	No	
Did the Standing Committee overturn any of the Scientific Methods Panel's ratings of Scientific Acceptability? If so, state the measure and why the measure was overturned.	No	
If a recommended measure is a related and/or competing measure, was a rationale provided for the Standing Committee's recommendation? If not, briefly explain.	N/A	
Were any measurement gap areas addressed? If so, identify the areas.	No	
Are there additional concerns that require CSAC discussion? If so, briefly explain.	No	

Appendix B: Measures Not Recommended for Endorsement

The table below lists the Committee's vote and rationale for measures not recommended for endorsement.

Legend: H = High; M = Moderate; L = Low; I = Insufficient

Measure	Voting Results	Standing Committee Rationale
NQF 2977 Hemodialysis Vascular Access, Standardized Fistula Rate (UM-KECC)	**Evidence** H-0; M-10; L-4; I-3 **Gap** H-3; M-14; L-0; I-0 **Reliability (Deemed Moderate by SMP)** Y-16; N-1 **Validity (Deemed Moderate by SMP)** Y-14; N-3 **Feasibility** H-11; M-5; L-0; I-0 **Usability and Use** *Use* Pass-16; No Pass-0 *Usability* H-2; M-11; L-2; I-2 **Post Comment Call Vote:** Evidence: H-0; M-3; L-1; I-14 Insufficient Evidence with Exception: Y-7; N-10 Overall Suitability for Endorsement: Y-7; N-11	The Committee re-voted on evidence criteria during the post-comment web meeting because the Committee did not reach consensus on the evidence criteria during the measure evaluation meeting. On the post-comment web meeting, the Standing Committee considered whether measure NQF #2977 qualified for the "Insufficient Evidence with Exception" pathway. The committee expressed concerns similar to those expressed during the measure evaluation meeting that the developer provided evidence based on updated guidelines from the National Kidney Foundation's (NKF) Kidney Disease Outcomes Quality Initiative (KDOQI), which included a downgrading of the evidence to support the measure to expert opinion. The Committee emphasized that maintenance measures should have stronger evidence to support measure endorsement and voted to not move the measure forward on evidence. As evidence is a must-pass criterion, this means that the Committee did not recommend the measure for endorsement.

Appendix C: NQF Member Expression of Support Results

Three NQF members provided their expression of support or not support. NQF members provided their expression of support for two measures under consideration and did not offer their support for one measure under consideration. Results for each measure are provided below.

0369: Standardized Mortality Ratio for Dialysis Facilities (Measure Steward/Developer)

Member Council	Support	Do Not Support	Total
QMRI	0	1	1

2977: Hemodialysis Vascular Access: Standardized Fistula Rate (Measure Steward/Developer)

Member Council	Support	Do Not Support	Total
QMRI	1	0	1

2978: Hemodialysis Vascular Access: Long-term Catheter Rate (Measure Steward/Developer)

Member Council	Support	Do Not Support	Total
QMRI	1	0	1

Appendix D: Details of Measure Evaluation

Rating Scale: H=High; **M**=Moderate; **L**=Low; **I**=Insufficient; **NA**=Not Applicable

Measures Recommended

0369 Standardized Mortality Ratio for Dialysis Facilities

Submission

Description: Standardized mortality ratio is defined to be the ratio of the number of deaths that occur for Medicare ESRD dialysis patients treated at a particular facility to the number of deaths that would be expected given the characteristics of the dialysis facility's patients and the national norm for dialysis facilities. This measure is calculated as a ratio but can also be expressed as a rate.
When used for public reporting, the measure calculation will be restricted to facilities with greater than three expected deaths in the reporting year. This restriction is required to ensure patients cannot be identified due to small cell size.
Numerator Statement: Number of deaths among eligible patients at the facility during the time period.
Denominator Statement: Number of deaths that would be expected among eligible dialysis patients at the facility during the time period given the national average mortality rate and the patient mix at the facility.
Exclusions: N/A
Adjustment/Stratification: Statistical Risk Model
Level of Analysis: Facility
Setting of Care: Other
Type of Measure: Outcome
Data Source: Claims, Registry Data
Measure Steward: Centers for Medicare & Medicaid Services

STANDING COMMITTEE MEETING 06/16/2020, 06/18/2020

1. Importance to Measure and Report: The measure meets the importance criteria

(1a. Evidence, 1b. Performance Gap)

1a. Evidence: **Pass-14; No Pass-1**; 1b. Performance Gap: **H-2; M-14; L-0; I-0**

Rationale:

- Within the submission, the developer indicated that there are numerous dialysis care processes that can influence the likelihood of a patient dying. The processes include the following:
  - Inadequate processes related to fluid management/removal: Inadequate control of total body fluid balance and fluid removal can result in fluid overload and congestive heart failure, increasing the possibility of death.
  - Inadequate infection prevention: Inadequate infection prevention processes, including suboptimal management of vascular access, can lead to bacteremia or septicemia, increasing the possibility of death.
  - Inadequate dialysis.: Failure to maintain processes to ensure adequate dialysis can lead to low Kt/V (K – dialyzer clearance of urea. t – dialysis time. V – volume of distribution of urea), increasing the possibility of death.
- The Committee commented on the updated evidence and citations provided by the developer, stating that there were no particular concerns regarding evidence for the measure.
- The average standardized mortality ratio (SMR) remained stable across years and during the 2015-2018 period.
  - The average SMR varied from 1.00 to 1.01.
  - However, within any given year, there was a substantial gap in performance as SMR varied widely across facilities, with the 10th decile being as low as 0.55 and the 90th decile being as high as 1.50.
- The Committee observed that there is an appropriate measure performance gap and that there were disparities in regard to race and ethnicity.

2. Scientific Acceptability of Measure Properties: The measure meets the scientific acceptability criteria

(2a. Reliability - precise specifications, testing; 2b. Validity - testing, threats to validity

0369 Standardized Mortality Ratio for Dialysis Facilities

2a. Reliability: **Yes-14; No-2**; 2b. Validity: **Yes-12; No-3**

Rationale:

- This measure was deemed complex and was evaluated by the NQF Scientific Methods Panel (SMP).
  - Vote for reliability – Moderate (H-2; M-5; L-1; I-0)
  - Vote for validity – High (H-4; M-4; L-1; I-0)
- Reliability testing conducted at the measure score level by calculating an interunit reliability (IUR) with bootstrapping; minimum 3 deaths/year to be included: IUR = 0.5, PIUR = 0.77
- Validity testing conducted at the measure score level by assessing the relationship of the measure to other performance measures using Spearman correlations: (all statistically significant)
  - Vascular Access: Standardized Fistula Rate (SFR): -0.08 Kt/V≥1.2: -0.16
  - Vascular Access: Long-Term Catheter Rate: 0.07
  - Standardized Hospitalization Ratio (SHR): 0.15
  - Standardized Readmissions Ratio (SRR): 0.08
  - Standardized Transfusion Ratio (STrR): 0.16
- The Committee expressed concerns related to the representation of pediatric patients within this measure, noting that this only represented 0.2% of the data.
- The Committee also noted the measure's complexity, expressing concern that the number of inputs may make it difficult to identify what interventions are resulting in improved mortality.
- The Committee asked the developer to comment on the inclusion of Medicare populations and the use of only inpatient data to determine prevalent comorbidities. The developer clarified that only inpatient claims were used for the measure and that potential comorbidities were accounted for in the measure. A sensitivity analysis demonstrated inpatient claims had more predictive impact than outpatient claims.
- Concerns posed by the Committee included the exclusion of non-Medicare patients and the use of in-patient claims data in the measure.

3. Feasibility: H-7; M-6; L-1; I-1

(3a. Clinical data generated during care delivery; 3b. Electronic sources; 3c. Susceptibility to inaccuracies/ unintended consequences identified 3d. Data collection strategy can be implemented)

Rationale:

- Data elements are normally collected while administrating care to patients. Data is coded by someone other than the data collector.
- Committee expressed no concerns.

4. Use and Usability

4a. Use; 4a1. Accountability and transparency; 4a2. Feedback on the measure by those being measured and others; 4b. Usability; 4b1. Improvement; 4b2. The benefits to patients outweigh evidence of unintended negative consequences to patients)

4a. Use: **Pass-15; No Pass-0** *4b. Usability:* **H-0; M-9; L-6; I-0**

Rationale:

- The measure is currently used for public reporting in Dialysis Facility Compare
- The Committee commented on the usefulness of mortality as a quality measure generally but stated no specific concerns related to usability and use.

5. Related and Competing Measures

- No related or competing measures noted.

6. Standing Committee Recommendation for Endorsement: **Y-11**; **N-4**

7. Public and Member Comment

- Commenters requested that pediatric patients and persons on hospice be removed from the measure. Concerns were also raised regarding the standardized mortality ratio's reliability, validity (risk model), specifications, and harmonization issues with CMS's other standardized measures.

0369 Standardized Mortality Ratio for Dialysis Facilities
8. Consensus Standards Approval Committee (CSAC) Vote: Y-X; N-X (Month, Date, Year: [Endorsed or Not Endorsed])
9. Appeals

2978 Hemodialysis Vascular Access: Long-Term Catheter Rate

Submission

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

Numerator Statement: 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.

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

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

The following exclusions are implicit in the denominator definition:

• Pediatric patients (<18 years old)

• Patients on peritoneal dialysis

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

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

• Patients with a catheter that have limited life expectancy

• Patients under hospice care in the current reporting month

• Patients with metastatic cancer in the past 12 months

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

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

Adjustment/Stratification: No risk adjustment or risk stratification
Level of Analysis: Facility
Setting of Care: Other
Type of Measure: Outcome: Intermediate Clinical Outcome
Data Source: Claims, Registry Data
Measure Steward: Centers for Medicare & Medicaid Services

STANDING COMMITTEE MEETING 06/16/2020, 06/18/2020

1. Importance to Measure and Report: <u>The measure meets the importance criteria</u>

(1a. Evidence, 1b. Performance Gap)

1a. Evidence: **H-0; M-15; L-0; I-2;** 1b. Performance Gap: **H-3; M-14; L-0; I-0**

<u>Rationale</u>:

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

2978 Hemodialysis Vascular Access: Long-Term Catheter Rate

  - 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 developer conducted a literature review to supplement the KDOQI guidelines (literature reviewed through 2017) by using the following search in PubMed: "Arteriovenous fistula OR venous catheter AND dialysis AND published January 1, 2017-2020 (present)."
  - In general, the recent articles offer additional support for the general concepts laid out in the KDOQI guidelines that AV fistula continue to be the preferred vascular access for most, but not all patients on dialysis, and that long-term catheters are associated with higher rates of infection and potentially mortality as well.
  - Long-term catheters are still viewed as the least desirable vascular access, primarily due to the increased risk of blood-stream infections with increased recognition of certain patient characteristics and scenarios where this access type may be the most appropriate.
- The Committee also noted that catheter lock and catheter cap solutions are not included in the evidence submission.
- The discussion on performance gap noted that the analysis of CROWNWeb data from 2018 indicated the facility-level mean percentage of patient-months with a long-term catheter was 12.4%.
- The Committee also reviewed submitted disparities information indicating that advanced age, female sex, ethnicity, dialysis vintage, and unemployment status are statistically significant predictors for odds of long-term catheter use.

2. Scientific Acceptability of Measure Properties: <u>The measure meets the scientific acceptability criteria</u>

(2a. Reliability - precise specifications, testing; 2b. Validity - testing, threats to validity

2a. Reliability: **Yes-17; No-0;** 2b. Validity: **Yes-15 ; No-1**

<u>Rationale</u>:

- This measure was deemed complex and was evaluated by the SMP.
  - Vote for reliability – Moderate (H-4; M-5; L-0; I-0)
  - Vote for validity – Moderate (H-1; M-6; L-2; I-0)
- Reliability testing conducted at the measure score level by calculating an IUR with bootstrapping; IUR = 0.76, No PIUR was provided.
- Validity testing conducted at the measure score level by assessing the relationship between facility level quintiles of performance scores and the SMR and SHR using Poisson regression:
  - SMR: The relative risk of mortality showed statistically significant increases as the performance measure quintile increased from the reference group (combined Q1 and Q2) to quintile 5.
    - Quintile 3, RR = 1.03 (95% CI: 1.01, 1.05; p = 0.004)
    - Quintile 4, RR = 1.02 (95% CI: 1.00, 1.04; p = 0.063)
    - Quintile 5, RR = 1.08 (95% CI: 1.05, 1.10; p<0.001).
  - SHR: The relative risk of hospitalization increased as the performance measure quintile increased from the reference group (combined Q1 and Q2).
    - Quintile 3, RR = 1.05 (95% CI: 1.05, 1.06; p<0.001)
    - Quintile 4, RR = 1.07 (95% CI: 1.06, 1.08; p<0.001)
    - Quintile 5, RR = 1.10 (95% CI: 1.09, 1.10; p<0.001).
- The Committee expressed no concerns with reliability.
- In the discussion on validity, the Committee noted the relationship between facility level quintiles of performance scores and the SMR and SHR using Poisson regression.
- The Committee noted that any missing vascular access information in the performance data is assumed to be catheter use. The developer clarified that this is to encourage providers to ensure that vascular access route is documented, noting that this is a relatively small portion of providers representing less than 2% of those measured.
- The Committee expressed some concerns related to the comorbidity conditions, namely that the measure is not adjusted.

2978 Hemodialysis Vascular Access: Long-Term Catheter Rate
○ The Committee generally agreed that the exclusion of comorbidities and lack of risk adjustment is correct. ○ The Committee also discussed that the identification of differences in population needs related to vascular access may need stratification. ○ The developer noted that the factors related to risk adjustment are primarily due to appropriateness of fistula use thus risk adjustment would be appropriate for the fistula measure and that exclusions are more appropriate for a catheter measure. • The exclusions are for pediatrics, hospice care, and comorbidities associated with limited life expectancy. • The Committee also discussed missing data and its impact on validity, as well as the impact of patient choice in the presence of known risks. • Severity of cardiovascular disease and heart failure was also discussed as potential inclusions in modelling, but the developer noted that they have not been successful in getting appropriate ICD-10 codes with sufficient detail to allow for this.
3. Feasibility: H-10; M-6; L-0; I-0 *(3a. Clinical data generated during care delivery; 3b. Electronic sources; 3c. Susceptibility to inaccuracies/ unintended consequences identified 3d. Data collection strategy can be implemented)* Rationale: • Data collection was noted to be conducted via claims and CROWNWeb with no concerns expressed by the Committee related to feasibility.
4. Use and Usability *4a. Use; 4a1. Accountability and transparency; 4a2. Feedback on the measure by those being measured and others; 4b. Usability; 4b1. Improvement; 4b2. The benefits to patients outweigh evidence of unintended negative consequences to patients)* 4a. Use: **Pass-16; No Pass-0** *4b. Usability:* **H-0; M-14; L-1; I-1** Rationale: • The measure was noted to be used in Dialysis Facility Compare and prospective inclusion in ESRD QIP in 2021 with no concerns expressed on the measure's current use. • Related to usability, the Committee noted that patient choice remains a challenge as a potential unintended consequence.
5. Related and Competing Measures • No competing measures noted.
6. Standing Committee Recommendation for Endorsement: Y-16; N-0
7. Public and Member Comment • Commenters suggested excluding from the denominator patients evaluated by vascular surgery but not eligible for arteriovenous fistula (AVF) due to either being a poor surgical candidate (e.g., having a lack of vessels amenable to fistula creation). They also suggested excluding patients who refuse AVF creation, as well as patients on hospice, with end-state renal disease, and pediatric populations, noting that the measure is not person-focused, as it assumes that AVF is the best option for every individual and their situation, which may not always be the case. Commenters also recommended refining the measure to address non-infectious complications.
8. Consensus Standards Approval Committee (CSAC) Vote: Y-X; N-X (Month, Date, Year: [Endorsed or Not Endorsed])
9. Appeals

Measures Not Recommended

2977 Hemodialysis Vascular Access: Standardized Fistula Rate

Submission

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

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.

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.

The following exclusions that implicit in the denominator definition:

- 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

Adjustment/Stratification:
Level of Analysis: Facility
Setting of Care: Other
Type of Measure: Outcome: Intermediate Clinical Outcome
Data Source: Claims, Registry Data
Measure Steward: Centers for Medicare & Medicaid Services

STANDING COMMITTEE MEETING 06/16/2020, 06/18/2020

1. Importance to Measure and Report: <u>The measure does not meet the importance criteria</u>

(1a. Evidence, 1b. Performance Gap)

1a. Evidence: **H-0; M-3; L-1; I-14**; 1b. Evidence with Exception: **Y-7; N-10; 1c.** Performance Gap: **H-3; M-14; L-0; I-0**

<u>Rationale</u>:

- The developer provided updated evidence from the 2019 National Kidney Foundation's (NKF) Kidney Disease Outcomes Quality Initiative (KDOQI) Clinical Practice Guideline for Vascular Access.
- 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. The guidelines state the following:
    - AV fistulas have the lowest rate of thrombosis and require the fewest interventions
    - Cost of AV fistula use and maintenance is the lowest
    - Fistulas have the lowest rates of infection
    - Fistulas are associated with the highest survival and lowest hospitalization rates
- Since the evidence for the above guidelines has been rated as either low or moderate with many of the guidelines relying on expert opinion, the developers also conducted a literature review to supplement the KDOQI guidelines (literature reviewed through 2017).

2977 Hemodialysis Vascular Access: Standardized Fistula Rate

- The reviewed articles offered 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 long-term catheters are associated with higher rates of infection and potentially mortality as well.
- The Committee noted that fistula remains the preferred access route for most dialysis patients over grafts and catheters.
    - The Committee expressed concern that the current fistula rate of 64% may be indicative that the remaining opportunities for improvement include many patients for whom fistula may not be the best route, such as those in hospice care, end-stage liver disease, or cancer.
    - The Committee expressed concern that the developer provided evidence based on updated guidelines from the National Kidney Foundation's (NKF) Kidney Disease Outcomes Quality Initiative (KDOQI), which included a downgrading of the evidence to support the measure to expert opinion.
    - It was noted that the developer supplemented the guidelines with literature that supported the measure focus.
- For performance gap, the Committee noted that, by the middle of 2017, 62.8% of prevalent hemodialysis patients were dialyzing with an AV fistula.
- For disparities, Hispanic ethnicity was associated with higher odds of fistula use whereas black communities are about 31% less likely to have fistulas than white ones.
- The Committee revoted on the measure during September 22, 2020 post-comment web meeting and did not recommend the measure for endorsement due to downgrading of evidence.

2. Scientific Acceptability of Measure Properties: <u>The measure meets the Scientific Acceptability criteria</u>

(2a. Reliability - precise specifications, testing; 2b. Validity - testing, threats to validity

2a. Reliability: **Yes-16; No-1**; 2b. Validity: **Yes-14; No-3**

<u>Rationale</u>:

- This measure was deemed complex and was evaluated by the NQF Scientific Methods Panel (SMP).
    - Vote for reliability – Moderate (H-4; M-5; L-0; I-0)
    - Vote for validity – Moderate (H-1; M-7; L-1; I-0)
- The Committee noted the score level reliability of the measure based on the IUR to be 0.755.
    - The developer also noted that their analyses produced a PIUR about 0.95 as well, though this was not included in the submission.
    - The Committee did not express any concerns related to the reliability.
- In the discussion on validity, the Committee noted the relationship between facility level quintiles of performance scores and the SMR and SHR using Poisson regression.
- The Committee noted that the risk adjustment is based on a multivariate logistic regression model.
    - The adjustment is made for age, BMI at incident, nursing home status, nephrologist's care prior to ESRD, duration of ESRD, diabetes as primary cause of ESRD, comorbidities, and two binary indicators including missing a CMS-2728 form and an indicator for if at least one of the comorbidities were present.
    - The common risk effects are assumed in order to improve computational stability in estimating facility-specific effects.
- The Committee noted 23% of data missingness and expressed a concern.
    - The developer noted that this is because the measure includes patients without Medicare coverage for whom comorbidities cannot be calculated, but they are included in the model to reduce bias.
    - The Committee considered the loss of information as a part of seeking balance in measuring an entire population and ensuring accuracy in the risk model and the presence of an adjustor in the model for those without comorbidity data.

3. Feasibility: H-11; M-5; L-0; I-0

(3a. Clinical data generated during care delivery; 3b. Electronic sources; 3c. Susceptibility to inaccuracies/ unintended consequences identified 3d. Data collection strategy can be implemented)

2977 Hemodialysis Vascular Access: Standardized Fistula Rate
Rationale: • The Committee did not express any concerns related to feasibility, noting that all reviewers considered the feasibility to be high.
4. Use and Usability *4a. Use; 4a1. Accountability and transparency; 4a2. Feedback on the measure by those being measured and others; 4b. Usability; 4b1. Improvement; 4b2. The benefits to patients outweigh evidence of unintended negative consequences to patients)* 4a. Use: **Pass-16; No Pass-0** *4b. Usability:* **H-2; M-11; L-2; I-2** Rationale: • The Committee express concerns related to use, referencing its long use in federal accountability programs. • The Committee noted an unintended consequence of potentially limiting patient choice when they may prefer a catheter due to downward pressure on clinicians to achieve a high fistula rate.
5. Related and Competing Measures • No competing measures noted.
6. Standing Committee Recommendation for Endorsement: **Y-7**; **N-11** • The Standing Committee voted to not recommend the measure for endorsement at the post-comment web meeting on September 22, 2020. The measure failed on evidence—a must-pass criterion.
7. Public and Member Comment • Commenters suggested excluding from the denominator patients evaluated by vascular surgery but not eligible for arteriovenous fistula (AVF) due to either being a poor surgical candidate (e.g., having a lack of vessels amenable to fistula creation) and patients who refuse AVF creation. Since this measure did not reach consensus for the Evidence criterion, commenters encouraged NQF to consider the "Insufficient Evidence with Exception" pathway towards endorsement.
8. Consensus Standards Approval Committee (CSAC) Vote: Y-X; N-X (Month, Date, Year: [Endorsed or Not Endorsed])
9. Appeals

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Renal
Spring 2020 Review Cycle

CSAC Review and Endorsement

November 17, 2020

Funded by the Centers for Medicare and Medicaid Services under contract HHSM-500-2017-00060I Task Order HHSM-500-T0001.

NATIONAL QUALITY FORUM

Standing Committee Recommendations

- Three measures reviewed for Spring 2020
  - Three measures reviewed by the Scientific Methods Panel
- Two measures recommended for endorsement
  - **NQF 0369** Standardized Mortality Ratio for Dialysis Facilities (Maintenance Measure)
  - **NQF 2978** Hemodialysis Vascular Access: Long-Term Catheter Rate (Maintenance Measure)
- One measure not recommended for endorsement
  - **NQF 2977** Hemodialysis Vascular Access: Standardized Fistula Rate (Maintenance Measure)

NATIONAL QUALITY FORUM

Overarching Issues

- Score Level Reliability Methods: IUR and PIUR
  - The Committee considered whether PIUR is appropriate as a measure of score level reliability analysis since it does not determine if providers are distinguishable from one another. Its best use is in determining the appropriateness of the measure in cases when the majority of providers in a sample do not have a high IUR rating.
- Downgrading of Evidence
  - During the most recent update, KDOQI conducted an in-depth review of the evidence base for the recommendations within the guideline, including a systematic review of the literature. This resulted in downgraded evidence that had previously been ranked as high to expert opinion for the measure focus of two measures reviewed for maintenance of endorsement by the Committee this cycle. The Committee felt it especially important to carefully consider the implications of the downgrading of evidence.
- Preferred Routes of Vascular Access for Hemodialysis
  - The Committee noted that measurement in this domain could create unintended consequences for patients for whom an AVF may not be the most desirable approach due to downward pressure on clinicians to order them—even where there is a more patient-centered option.

Public and Member Comment and Member Expressions of Support

- Nine comments received
  - Commenters expressed several concerns related to the denominator used, stating that certain populations such as patients not eligible for arteriovenous fistula (AVF), persons on hospice, and pediatric populations be excluded.
  - Commenters called for more measures applicable to pediatric patients.
  - Commenters recommended refining measures to address non-infectious complications.
- Three NQF member of expressions of support received
  - Two in support and one did not support

NATIONAL QUALITY FORUM

Questions?

- Project team:
  - Samuel Stolpe, PharmD, MPH, Senior Director
  - Janaki Panchal, MSPH, Manager
  - Teja Vemuganti, MPH, Analyst
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THANK YOU.

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Renal, Spring 2020 Cycle: CDP Report

DRAFT REPORT FOR CSAC REVIEW
NOVEMBER 17, 2020

This report is funded by the Centers for Medicare and Medicaid Services under contract HHSM-500-2017-00060I Task Order HHSM-500-T0001

http://www.qualityforum.org

Contents

Executive Summary

Renal disease is a leading cause of morbidity and mortality in the United States. More than 36 million adults (14 percent of the adult population) have chronic kidney disease (CKD).[1] Untreated, CKD can progress to an advanced state of kidney dysfunction known as end-stage renal disease (ESRD) and a host of other health complications such as cardiovascular disease, hyperlipidemia, anemia, and metabolic bone disease. Currently, over half a million people in the U.S. have received a diagnosis of ESRD.[1] Considering the high mortality rates and high healthcare utilization and costs associated with ESRD, the need to focus on quality measures for patients with renal disease is of the highest importance.

Quality measurement plays a central role in facilitating improvement in the quality of care received by CKD patients, especially those on hemodialysis (HD). NQF-endorsed kidney care measures are used in several quality and performance improvement programs administered by the Centers for Medicare and Medicaid Services (CMS), such as Dialysis Facility Compare and the ESRD Quality Incentive Program (ESRD QIP).

This project sought to identify and endorse performance measures for accountability and quality improvement that address conditions, treatments, interventions, or procedures relating to kidney disease.

For the spring 2020 measure review cycle, the Standing Committee evaluated three measures undergoing maintenance review against NQF's standard evaluation criteria. The Committee recommended two measures for endorsement, and the Committee did not recommend one measure for endorsement. The measures recommended for endorsement are:

- **NQF 0369** Standardized Mortality Ratio for Dialysis Facilities (University of Michigan Kidney Epidemiology and Cost Center (UM-KECC))
- **NQF 2978** Hemodialysis Vascular Access, Long-Term Catheter Rate (UM-KECC)

The measure not recommended for endorsement is:

- **NQF 2977** Hemodialysis Vascular Access, Standardized Fistula Rate (UM-KECC)

Brief summaries of the measures currently under review are included in the body of this report; detailed summaries of the Committee's discussion and ratings of the criteria for each measure are in Appendix A.

Introduction

Kidney disease has long been a leading cause of morbidity and mortality in the U.S. More than 36 million adults—representing more than 14 percent of the adult population—have chronic kidney CKD.[1] Untreated, CKD can progress to an advanced state of kidney dysfunction known as end-stage renal disease (ESRD) and a host of other health complications such as cardiovascular disease, hyperlipidemia, anemia and metabolic bone disease. Currently, over half a million people in the U.S. have received a diagnosis of ESRD.[1] Considering the high mortality rates and high healthcare utilization and costs associated with ESRD, the need to focus on quality measures for patients with renal disease is particularly important.

Moreover, there are preferred processes of care associated with vascular access for patients with CKD that use hemodialysis. The current expert opinion is that arteriovenous fistulas (AVF) are preferred over grafts and catheters, with catheters being the least desirable option due to increased patient susceptibility to infection.[2] Nonetheless, approaching vascular access with a patient-centered approach that considers patient circumstances and conditions—such as those with overall poorer prognoses and limited life expectancy—is a key issue in the provision of high-quality hemodialysis care.[3]

In 1972, President Richard Nixon signed section 2991 of Public Law 92-603, which established ESRD as the only healthcare condition that Medicare covers for people under the age of 65.[4] Under this provision, people are eligible for Medicare regardless of their age if their kidneys are no longer functioning, if they need regular dialysis, or if they have had a kidney transplant. The United States continues to spend significant resources on care and treatment of CKD and ESRD. In 2010, total Medicare spending rose 6.5 percent to $522.8 billion, and expenditures for ESRD rose 8 percent to $32.9 billion.[1]

NQF Portfolio of Performance Measures for Renal Conditions

The Renal Standing Committee (Appendix C) oversees NQF's portfolio of Renal measures (Appendix B). This portfolio contains 21 measures: five process measures, 13 intermediate outcome measures, and three outcome measures (see table below).

Table 1. NQF Portfolio of Measures for Renal Conditions

	Process	Intermediate Outcome	Outcome
Hemodialysis	1	2	0
Hemodialysis – Pediatric	0	1	0
Hemodialysis Vascular Access	0	4	0
Dialysis Monitoring	1	1	0
Dialysis Monitoring - Pediatric	2	1	0
Peritoneal Dialysis	0	4	0
Patient Safety	0	0	3
Treatment Initiation	1	0	0
Total	5	13	3

Additional renal measures have been assigned to other projects. These include measures related to admissions, readmissions and emergency department utilization (*All-Cause Admissions and Readmissions*), various diabetes assessment and screening measures (*Primary Care & Chronic Illness*), eye care measures (*Primary Care & Chronic Illness*), ACEI/ARB medication measures (*Cardiovascular and Primary Care & Chronic Illness*), complications and outcomes measures (*Cardiovascular, Patient Experience & Function, and Surgery*), and cost and resource use measures (*Cost and Efficiency*).

Renal Measure Evaluation

On June 16 and 18, 2020 the Renal Standing Committee evaluated three measures undergoing maintenance review against NQF's standard measure evaluation criteria.

Table 2. Renal Measure Evaluation Summary

	Maintenance	New	Total
Measures under consideration	3	0	3
Measures recommended for endorsement	2	0	2
Measures not recommended for endorsement	1	0	1
Reasons for not recommending	Importance – 1 Scientific Acceptability – 0 Use – 0 Overall Suitability – 0 Competing Measures – 0	Importance – 0 Scientific Acceptability – 0 Use – 0 Overall Suitability – 0 Competing Measures – 0	

Comments Received Prior to Committee Evaluation

NQF solicits comments on endorsed measures on an ongoing basis through the Quality Positioning System (QPS). In addition, NQF solicits comments for a continuous 16-week period during each evaluation cycle via an online tool located on the project webpage. For this evaluation cycle, the commenting period opened on April 24, 2020 and closed on August 25, 2020. As of June 5, 2020, no comments were submitted.

Comments Received After Committee Evaluation

The continuous 16-week public commenting period with NQF member support closed on August 25, 2020. Following the Committee's evaluation of the measures under consideration, NQF received nine comments from four member organizations and individuals pertaining to the draft report and to the measures under consideration. All comments for each measure under consideration have been summarized in Appendix A.

Throughout the 16-week continuous public commenting period, NQF members had the opportunity to express their support ('support' or 'do not support') for each measure submitted for endorsement

consideration to inform the Committee's recommendations. Three NQF members provided their expression of support.

Overarching Issues

During the Standing Committee's discussion of the measures, several overarching issues emerged that were factored into the Committee's ratings and recommendations for multiple measures and are not repeated in detail with each individual measure.

Score Level Reliability Methods: IUR and PIUR

One of the measures under consideration utilized interunit reliability (IUR) testing along with an additional analysis of the profile interunit reliability (PIUR). IUR testing is a common score-level reliability test that produces a signal-to-noise analysis. It was noted that PIUR provides a complimentary analysis that shows the measures' ability to detect outliers. The Committee considered whether PIUR is appropriate as a measure of score level reliability analysis since it does not determine if providers are distinguishable one from another. In fact, its best use is in determining the appropriateness of the measure in cases when the majority of providers in a sample do not have a high IUR rating.

The developer noted that the accountability application determines whether the measure is sufficiently reliable for a given set of providers. For example, if the provider sample is highly clustered around a mean, an incentive (or disincentive) program for providers who perform significantly outside of the mean may be considered reliable, where a program that rewarded providers simply by their ranking may not be reliable because of the clustering of providers. These reflections resulted in the Committee discussing a potential need for NQF to consider specifying the intended use of a given measure and include application as part of endorsement consideration. NQF's use and usability criteria assesses the extent to which potential audiences (e.g., consumers, purchasers, providers, policymakers) 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. NQF's current process grants endorsement and signals the measure is appropriate for use in any accountability application.

Downgrading of Evidence

The Committee considered two measures that were based on updated guidelines from the National Kidney Foundation's (NKF) Kidney Disease Outcomes Quality Initiative (KDOQI). During the most recent update, KDOQI conducted an in-depth review of the evidence base for the recommendations within the guideline, including a systematic review of the literature. This resulted in downgraded evidence that had previously been ranked as high to expert opinion for the measure focus of NQF 2977 and 2978reviewed for maintenance of endorsement by the Committee this cycle. The measure developer supplemented the systematic review in KDOQI with additional journal articles. Nonetheless, the Committee felt it is especially important to carefully consider the implications of the downgrading of evidence for these two measures, ultimately concluding that the evidence to support the use of fistulas was not as strong as the evidence against the use of catheters for vascular access.

Preferred Routes of Vascular Access for Hemodialysis

The Committee noted that the preferred route of vascular access is via an AVF. The Committee expressed that patient preference will be a confounding factor in any measure of vascular access. Moreover, the Committee also noted that there are many instances when an AVF may not be the preferred access route for certain patients, even in the face of known risks. The Committee noted that measurement in this domain could create unintended consequences for patients for whom an AVF may not be the most desirable approach due to downward pressure on clinicians to order them—even where there is a more patient-centered option. The Committee also noted that advancement in its technology (e.g. catheter locks) will create additional need for careful consideration on the part of the measure developer to consider the implications in overall undesirability associated with catheter use.

Summary of Measure Evaluation

The following brief summaries of the measure evaluation highlight the major issues that the Committee considered. Details of the Committee's discussion and ratings of the criteria for each measure are included in Appendix A.

0369 Standardized Mortality Ratio for Dialysis Facilities (University of Michigan Kidney Epidemiology and Cost Center): Recommended

Description: Standardized mortality ratio is defined to be the ratio of the number of deaths that occur for Medicare ESRD dialysis patients treated at a particular facility to the number of deaths that would be expected given the characteristics of the dialysis facility's patients and the national norm for dialysis facilities. This measure is calculated as a ratio but can also be expressed as a rate. When used for public reporting, the measure calculation will be restricted to facilities with greater than three expected deaths in the reporting year. This restriction is required to ensure patients cannot be identified due to small cell size. **Measure Type**: Outcome; **Level of Analysis**: Facility; **Setting of Care**: Other; **Data Source**: Claims, Registry Data

The Standing Committee recommended the measure for continued endorsement. The discussion of the measure began with an overview and a detailed review of the evidence submission. The Committee commented on the updated evidence and citations provided by the developer, stating that there were no particular concerns regarding evidence. The Committee observed that there is an appropriate measure performance gap and that there were disparities in regard to race and ethnicity. The committee asked the developer why the combined four-year standardized mortality ratio (SMR) was different from the four-individual year SMRs. The developer clarified this is a four-year measure and that the difference is due to more data available for the four-year SMR compared to the individual one-year SMRs. The developer provided a presentation to the Committee on the score level reliability methodologies used, namely IUR and PIUR. The Committee noted that IUR is useful for signal-to-noise analysis while PIUR is used to determine a measure's capability of identifying outliers. The Committee also noted that this measure has been evaluated by the Scientific Methods Panel (SMP) and was given a moderate rating for reliability and a high rating for validity.

The Committee expressed concerns related to the representation of pediatric patients within this measure, noting that this only represented 0.2% of the data. The Committee also noted the measure's complexity, expressing concern that the number of inputs may make it difficult to identify what

interventions are resulting in improved mortality. The Committee asked the developer to comment on the inclusion of Medicare populations and the use of inpatient data alone (rather than also including outpatient data) to determine prevalent comorbidities. The developer clarified that only inpatient claims were used and that potential comorbidities were accounted for in the measure. A sensitivity analysis demonstrated inpatient claims had more predictive impact than outpatient claims. In regard to validity, the Committee noted that the SMP stated that the correlations were statistically significant and directionally appropriate. Concerns posed by the Committee included the exclusion of non-Medicare patients and the use of in-patient claims data in the measure. The Committee stated no concerns on feasibility and use. The committee commented on the usefulness of mortality as a quality measure generally but stated no specific concerns related to usability and use.

2977 Hemodialysis Vascular Access: Standardized Fistula Rate (University of Michigan Kidney Epidemiology and Cost Center): Not Recommended

Description: Adjusted percentage of adult hemodialysis patient-months using an autogenous AVF as the sole means of vascular access. **Measure Type**: Outcome: Intermediate Clinical Outcome; **Level of Analysis**: Facility; **Setting of Care**: Other; **Data Source**: Claims, Registry Data

The Standing Committee did not recommend the measure for endorsement because the measure did not pass on evidence—a must-pass criterion.

The discussion of this measure began with an overview and a review of the evidence. The Committee noted that fistula remains as the preferred access route for most dialysis patients over grafts and catheters. The Committee expressed concern that the current fistula rate of 64% may be indicative that the remaining opportunities for improvement may include many patients for whom fistula may not be the best route, such as those in hospice care, end-stage liver disease, or cancer. The Committee expressed concern that the developer provided evidence based on updated guidelines from the National Kidney Foundation's (NKF) Kidney Disease Outcomes Quality Initiative (KDOQI) which included a downgrading of the evidence to support the measure to expert opinion. It was noted that the developer supplemented the guidelines with literature that supported the measure focus. In the discussion on performance gap, the Committee noted that, by the middle of 2017, 62.8% of prevalent hemodialysis patients were dialyzing with an AVF. For disparities, Hispanic ethnicity was associated with higher odds of fistula use whereas black communities are about 31% less likely to have fistulas than white peers.

The Committee noted the score level reliability of the measure based on the IUR to be 0.75. The developer also noted that their analyses produced a PIUR of about 0.95 as well, though this was not included in the submission. The Committee did not express any concerns related to the reliability. In the discussion on validity, the Committee noted the relationship between facility level quintiles of performance scores and the SMR and standardized hospitalization rate (SHR) using Poisson regression. The Committee noted that the risk adjustment is based on a multivariate logistic regression model. The adjustment is made for age, BMI at incident, nursing home status, nephrologist's care prior to ESRD, duration of ESRD, diabetes as primary cause of ESRD, comorbidities, and two binary indicators including missing a CMS-2728 form and an indicator for if at least one of the comorbidities were present. Common risk effects are assumed in order to improve computational stability in estimating facility-specific effects. The Committee noted 23% of data were missing and expressed a concern. The

developer noted that this is because the measure includes patients without Medicare coverage for whom comorbidities cannot be calculated, but they are included in the model to reduce bias. The Committee considered the loss of information as a part of seeking balance in measuring an entire population and ensuring accuracy in the risk model and the presence of an adjustor in the model for those without comorbidity data. The Committee did not express any concerns related to feasibility, noting that all reviewers considered it to be high. The Committee expressed no concerns related to use, referencing its long use in federal accountability programs. The Committee noted an unintended consequence of potentially limiting patient choice when they may prefer a catheter due to downward pressure on clinicians to achieve a high fistula rate.

The Committee re-voted on evidence criteria during the post-comment web meeting because the Committee did not reach consensus on the evidence criteria during the measure evaluation meeting. On the post-comment web meeting, the Standing Committee considered whether measure NQF #2977 qualified for the "Insufficient Evidence with Exception" pathway. The committee expressed concerns similar to those expressed during the measure evaluation meeting that the developer provided evidence based on updated guidelines from the National Kidney Foundation's (NKF) Kidney Disease Outcomes Quality Initiative (KDOQI), which included a downgrading of the evidence to support the measure to expert opinion. The Committee emphasized that maintenance measures should have stronger evidence to support measure endorsement and voted to not move the measure forward on evidence. As evidence is a must-pass criterion, this means that the Committee did not recommend the measure for endorsement.

2978 Hemodialysis Vascular Access: Long-Term Catheter Rate (University of Michigan Kidney Epidemiology and Cost Center): Recommended

Description: Percentage of adult hemodialysis patient-months using a catheter continuously for three months or longer for vascular access. **Measure Type**: Outcome: Intermediate Clinical Outcome; **Level of Analysis**: Facility; **Setting of Care**: Other; **Data Source**: Claims, Registry Data

The Standing Committee recommended the measure for continued endorsement. This measure was noted to be a companion measure to NQF #2977. Following an overview, the Committee reviewed the evidence submitted to support the measure, which was also drawn from KDOQI guidelines and supplementary evidence from the literature provided by the developer. As with measure NQF #2977, the Committee noted that the evidence has been downgraded in the guidelines, but also noted that the evidence indicates increased infection associated with catheters. The Committee also noted that catheter lock and catheter cap solutions are not included in the evidence submission. The discussion on performance gap noted that the analysis of CROWNWeb data from 2018 indicated the facility-level mean percentage of patient-months with a long-term catheter was 12.4%. The Committee also reviewed submitted disparities information indicating that advanced age, female sex, ethnicity, dialysis vintage, and unemployment status are statistically significant predictors for odds of long-term catheter use. Related to reliability, the Committee noted very little change in the specifications since its last submission. The testing was conducted at the measure score level by calculating an IUR with bootstrapping. IUR was 0.76 with no PIUR provided.

In the discussion on validity, the Committee noted the relationship between facility level quintiles of performance scores and the SMR and SHR using Poisson regression. The Committee noted that any

missing vascular access information related to vascular access in the performance data is assumed to be catheter use. The developer clarified that this is to encourage providers to ensure that vascular access route is documented, noting that this is a relatively small portion of providers representing less than 2% of those measured. The SMP reviewed this measure and expressed some concerns related to the comorbidity conditions, namely that the measure is not adjusted for. The Committee generally agreed that the exclusion of comorbidities and lack of risk adjustment is correct. The Committee also discussed that the identification of differences in population needs related to vascular access may imply the need for stratification. The developer noted that the factors related to risk adjustment are primarily due to appropriateness of fistula use thus risk adjustment would be appropriate for the fistula measure, and exclusions are more appropriate for a catheter measure. The exclusions are for pediatrics, hospice care, and comorbidities associated with limited life expectancy. The Committee also discussed missing data and its impact on validity as well as the impact of patient choice in the presence of known risks. Severity of cardiovascular disease and heart failure was also discussed as potential inclusions in modelling, but the developer noted that they have not been successful in getting appropriate ICD-10 codes with sufficient detail to allow for this.

Data collection was noted to be conducted via claims and CROWNWeb with no concerns expressed by the Committee related to feasibility. The measure was noted to be used in Dialysis Facility Compare and prospective inclusion in ESRD QIP in 2021 with no concerns expressed on the measure's current use. Related to usability, the Committee noted that patient choice remains a challenge as a potential unintended consequence.

References

1 U.S. Renal Data System (USRDS). 2018 Annual Data Report: Epidemiology of Kidney Disease in the United States. Bethesda, M.

2 Fisher M, Golestaneh L, Allon M, et al. Prevention of Bloodstream Infections in Patients Undergoing Hemodialysis. *Clin J Am Soc Nephrol*. 2020;15(1):132-151.

3 Kalloo S, Blake PG, Wish J. A Patient-Centered Approach to Hemodialysis Vascular Access in the Era of Fistula First. *Semin Dial*. 2016;29(2):148-157.

4 CROWNWeb. CROWNWeb: History, Purpose, and Usage [video]. http://mycrownweb.org/help/about-crownweb/. Last accessed Decem.

Appendix A: Details of Measure Evaluation

Rating Scale: H=High; **M**=Moderate; **L**=Low; **I**=Insufficient; **NA**=Not Applicable

Measures Recommended

0369 Standardized Mortality Ratio for Dialysis Facilities

Submission | Specifications

Description: Standardized mortality ratio is defined to be the ratio of the number of deaths that occur for Medicare ESRD dialysis patients treated at a particular facility to the number of deaths that would be expected given the characteristics of the dialysis facility's patients and the national norm for dialysis facilities. This measure is calculated as a ratio but can also be expressed as a rate.

When used for public reporting, the measure calculation will be restricted to facilities with greater than three expected deaths in the reporting year. This restriction is required to ensure patients cannot be identified due to small cell size.

Numerator Statement: Number of deaths among eligible patients at the facility during the time period.

Denominator Statement: Number of deaths that would be expected among eligible dialysis patients at the facility during the time period given the national average mortality rate and the patient mix at the facility.

Exclusions: N/A

Adjustment/Stratification: Statistical Risk Model

Level of Analysis: Facility

Setting of Care: Other

Type of Measure: Outcome

Data Source: Claims, Registry Data

Measure Steward: Centers for Medicare & Medicaid Services

STANDING COMMITTEE MEETING 06/16/2020, 06/18/2020

1. Importance to Measure and Report: The measure meets the importance criteria

(1a. Evidence, 1b. Performance Gap)

1a. Evidence: **Pass-14; No Pass-1**; 1b. Performance Gap: **H-2; M-14; L-0; I-0**

Rationale:

- Within the submission, the developer indicated that there are numerous dialysis care processes that can influence the likelihood of a patient dying. The processes include the following:
  - Inadequate processes related to fluid management/removal: Inadequate control of total body fluid balance and fluid removal can result in fluid overload and congestive heart failure, increasing the possibility of death.
  - Inadequate infection prevention: Inadequate infection prevention processes, including suboptimal management of vascular access, can lead to bacteremia or septicemia, increasing the possibility of death.
  - Inadequate dialysis.: Failure to maintain processes to ensure adequate dialysis can lead to low Kt/V (K – dialyzer clearance of urea. t – dialysis time. V – volume of distribution of urea), increasing the possibility of death.
- The Committee commented on the updated evidence and citations provided by the developer, stating that there were no particular concerns regarding evidence for the measure.
- The average standardized mortality ratio (SMR) remained stable across years and during the 2015-2018 period.
  - The average SMR varied from 1.00 to 1.01.
  - However, within any given year, there was a substantial gap in performance as SMR varied widely across facilities, with the 10th decile being as low as 0.55 and the 90th decile being as high as 1.50.
- The Committee observed that there is an appropriate measure performance gap and that there were disparities in regard to race and ethnicity.

0369 Standardized Mortality Ratio for Dialysis Facilities

2. Scientific Acceptability of Measure Properties: The measure meets the scientific acceptability criteria

(2a. Reliability - precise specifications, testing; 2b. Validity - testing, threats to validity

2a. Reliability: **Yes-14; No-2**; 2b. Validity: **Yes-12; No-3**

Rationale:

- This measure was deemed complex and was evaluated by the NQF Scientific Methods Panel (SMP).
  - Vote for reliability – Moderate (H-2; M-5; L-1; I-0)
  - Vote for validity – High (H-4; M-4; L-1; I-0)
- Reliability testing conducted at the measure score level by calculating an interunit reliability (IUR) with bootstrapping; minimum 3 deaths/year to be included: IUR = 0.5, PIUR = 0.77
- Validity testing conducted at the measure score level by assessing the relationship of the measure to other performance measures using Spearman correlations: (all statistically significant)
  - Vascular Access: Standardized Fistula Rate (SFR): -0.08 Kt/V≥1.2: -0.16
  - Vascular Access: Long-Term Catheter Rate: 0.07
  - Standardized Hospitalization Ratio (SHR): 0.15
  - Standardized Readmissions Ratio (SRR): 0.08
  - Standardized Transfusion Ratio (STrR): 0.16
- The Committee expressed concerns related to the representation of pediatric patients within this measure, noting that this only represented 0.2% of the data.
- The Committee also noted the measure's complexity, expressing concern that the number of inputs may make it difficult to identify what interventions are resulting in improved mortality.
- The Committee asked the developer to comment on the inclusion of Medicare populations and the use of only inpatient data to determine prevalent comorbidities. The developer clarified that only inpatient claims were used for the measure and that potential comorbidities were accounted for in the measure. A sensitivity analysis demonstrated inpatient claims had more predictive impact than outpatient claims.
- Concerns posed by the Committee included the exclusion of non-Medicare patients and the use of in-patient claims data in the measure.

3. Feasibility: H-7; M-6; L-1; I-1

(3a. Clinical data generated during care delivery; 3b. Electronic sources; 3c. Susceptibility to inaccuracies/ unintended consequences identified 3d. Data collection strategy can be implemented)

Rationale:

- Data elements are normally collected while administrating care to patients. Data is coded by someone other than the data collector.
- Committee expressed no concerns.

4. Use and Usability

4a. Use; 4a1. Accountability and transparency; 4a2. Feedback on the measure by those being measured and others; 4b. Usability; 4b1. Improvement; 4b2. The benefits to patients outweigh evidence of unintended negative consequences to patients)

4a. Use: **Pass-15; No Pass-0** *4b. Usability:* **H-0; M-9; L-6; I-0**

Rationale:

- The measure is currently used for public reporting in Dialysis Facility Compare
- The Committee commented on the usefulness of mortality as a quality measure generally but stated no specific concerns related to usability and use.

5. Related and Competing Measures

- No related or competing measures noted.

6. Standing Committee Recommendation for Endorsement: **Y-11**; **N-4**

7. Public and Member Comment

- Commenters requested that pediatric patients and persons on hospice be removed from the measure. Concerns were also raised regarding the standardized mortality ratio's reliability, validity (risk model), specifications, and harmonization issues with CMS's other standardized measures.

0369 Standardized Mortality Ratio for Dialysis Facilities
8. Consensus Standards Approval Committee (CSAC) Vote: Y-X; N-X (Month, Date, Year: [Endorsed or Not Endorsed])
9. Appeals

2978 Hemodialysis Vascular Access: Long-Term Catheter Rate

Submission | Specifications

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

Numerator Statement: 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.

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

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

The following exclusions are implicit in the denominator definition:

• Pediatric patients (<18 years old)

• Patients on peritoneal dialysis

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

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

• Patients with a catheter that have limited life expectancy

• Patients under hospice care in the current reporting month

• Patients with metastatic cancer in the past 12 months

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

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

Adjustment/Stratification: No risk adjustment or risk stratification

Level of Analysis: Facility

Setting of Care: Other

Type of Measure: Outcome: Intermediate Clinical Outcome

Data Source: Claims, Registry Data

Measure Steward: Centers for Medicare & Medicaid Services

STANDING COMMITTEE MEETING 06/16/2020, 06/18/2020

1. Importance to Measure and Report: <u>The measure meets the importance criteria</u>

(1a. Evidence, 1b. Performance Gap)

1a. Evidence: **H-0; M-15; L-0; I-2;** 1b. Performance Gap: **H-3; M-14; L-0; I-0**

<u>Rationale</u>:

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

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  - 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 developer conducted a literature review to supplement the KDOQI guidelines (literature reviewed through 2017) by using the following search in PubMed: "Arteriovenous fistula OR venous catheter AND dialysis AND published January 1, 2017-2020 (present)."
  - In general, the recent articles offer additional support for the general concepts laid out in the KDOQI guidelines that AV fistula continue to be the preferred vascular access for most, but not all patients on dialysis, and that long-term catheters are associated with higher rates of infection and potentially mortality as well.
  - Long-term catheters are still viewed as the least desirable vascular access, primarily due to the increased risk of blood-stream infections with increased recognition of certain patient characteristics and scenarios where this access type may be the most appropriate.
- The Committee also noted that catheter lock and catheter cap solutions are not included in the evidence submission.
- The discussion on performance gap noted that the analysis of CROWNWeb data from 2018 indicated the facility-level mean percentage of patient-months with a long-term catheter was 12.4%.
- The Committee also reviewed submitted disparities information indicating that advanced age, female sex, ethnicity, dialysis vintage, and unemployment status are statistically significant predictors for odds of long-term catheter use.

2. Scientific Acceptability of Measure Properties: <u>The measure meets the scientific acceptability criteria</u>

(2a. Reliability - precise specifications, testing; 2b. Validity - testing, threats to validity

2a. Reliability: **Yes-17; No-0;** 2b. Validity: **Yes-15 ; No-1**

<u>Rationale</u>:

- This measure was deemed complex and was evaluated by the SMP.
  - Vote for reliability – Moderate (H-4; M-5; L-0; I-0)
  - Vote for validity – Moderate (H-1; M-6; L-2; I-0)
- Reliability testing conducted at the measure score level by calculating an IUR with bootstrapping; IUR = 0.76, No PIUR was provided.
- Validity testing conducted at the measure score level by assessing the relationship between facility level quintiles of performance scores and the SMR and SHR using Poisson regression:
  - SMR: The relative risk of mortality showed statistically significant increases as the performance measure quintile increased from the reference group (combined Q1 and Q2) to quintile 5.
    - Quintile 3, RR = 1.03 (95% CI: 1.01, 1.05; p = 0.004)
    - Quintile 4, RR = 1.02 (95% CI: 1.00, 1.04; p = 0.063)
    - Quintile 5, RR = 1.08 (95% CI: 1.05, 1.10; p<0.001).
  - SHR: The relative risk of hospitalization increased as the performance measure quintile increased from the reference group (combined Q1 and Q2).
    - Quintile 3, RR = 1.05 (95% CI: 1.05, 1.06; p<0.001)
    - Quintile 4, RR = 1.07 (95% CI: 1.06, 1.08; p<0.001)
    - Quintile 5, RR = 1.10 (95% CI: 1.09, 1.10; p<0.001).
- The Committee expressed no concerns with reliability.
- In the discussion on validity, the Committee noted the relationship between facility level quintiles of performance scores and the SMR and SHR using Poisson regression.
- The Committee noted that any missing vascular access information in the performance data is assumed to be catheter use. The developer clarified that this is to encourage providers to ensure that vascular access route is documented, noting that this is a relatively small portion of providers representing less than 2% of those measured.
- The Committee expressed some concerns related to the comorbidity conditions, namely that the measure is not adjusted.

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○ The Committee generally agreed that the exclusion of comorbidities and lack of risk adjustment is correct. ○ The Committee also discussed that the identification of differences in population needs related to vascular access may need stratification. ○ The developer noted that the factors related to risk adjustment are primarily due to appropriateness of fistula use thus risk adjustment would be appropriate for the fistula measure and that exclusions are more appropriate for a catheter measure. • The exclusions are for pediatrics, hospice care, and comorbidities associated with limited life expectancy. • The Committee also discussed missing data and its impact on validity, as well as the impact of patient choice in the presence of known risks. • Severity of cardiovascular disease and heart failure was also discussed as potential inclusions in modelling, but the developer noted that they have not been successful in getting appropriate ICD-10 codes with sufficient detail to allow for this.
3. Feasibility: H-10; M-6; L-0; I-0 *(3a. Clinical data generated during care delivery; 3b. Electronic sources; 3c. Susceptibility to inaccuracies/ unintended consequences identified 3d. Data collection strategy can be implemented)* Rationale: • Data collection was noted to be conducted via claims and CROWNWeb with no concerns expressed by the Committee related to feasibility.
4. Use and Usability *4a. Use; 4a1. Accountability and transparency; 4a2. Feedback on the measure by those being measured and others; 4b. Usability; 4b1. Improvement; 4b2. The benefits to patients outweigh evidence of unintended negative consequences to patients)* 4a. Use: **Pass-16; No Pass-0** *4b. Usability:* **H-0; M-14; L-1; I-1** Rationale: • The measure was noted to be used in Dialysis Facility Compare and prospective inclusion in ESRD QIP in 2021 with no concerns expressed on the measure's current use. • Related to usability, the Committee noted that patient choice remains a challenge as a potential unintended consequence.
5. Related and Competing Measures • No competing measures noted.
6. Standing Committee Recommendation for Endorsement: **Y-16**; **N-0**
7. Public and Member Comment • Commenters suggested excluding from the denominator patients evaluated by vascular surgery but not eligible for arteriovenous fistula (AVF) due to either being a poor surgical candidate (e.g., having a lack of vessels amenable to fistula creation). They also suggested excluding patients who refuse AVF creation, as well as patients on hospice, with end-state renal disease, and pediatric populations, noting that the measure is not person-focused, as it assumes that AVF is the best option for every individual and their situation, which may not always be the case. Commenters also recommended refining the measure to address non-infectious complications.
8. Consensus Standards Approval Committee (CSAC) Vote: Y-X; N-X (Month, Date, Year: [Endorsed or Not Endorsed])
9. Appeals

Measures Not Recommended

2977 Hemodialysis Vascular Access: Standardized Fistula Rate

Submission | Specifications

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

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.

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.

The following exclusions that implicit in the denominator definition:

• 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

Adjustment/Stratification:

Level of Analysis: Facility

Setting of Care: Other

Type of Measure: Outcome: Intermediate Clinical Outcome

Data Source: Claims, Registry Data

Measure Steward: Centers for Medicare & Medicaid Services

STANDING COMMITTEE MEETING 06/16/2020, 06/18/2020

1. Importance to Measure and Report: The measure does not meet the importance criteria

(1a. Evidence, 1b. Performance Gap)

1a. Evidence: **H-0; M-3; L-1; I-14**; 1b. Evidence with Exception: **Y-7; N-10; 1c.** Performance Gap: **H-3; M-14; L-0; I-0**

Rationale:

- The developer provided updated evidence from the 2019 National Kidney Foundation's (NKF) Kidney Disease Outcomes Quality Initiative (KDOQI) Clinical Practice Guideline for Vascular Access.
- 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. The guidelines state the following:
    - AV fistulas have the lowest rate of thrombosis and require the fewest interventions
    - Cost of AV fistula use and maintenance is the lowest
    - Fistulas have the lowest rates of infection
    - Fistulas are associated with the highest survival and lowest hospitalization rates

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- Since the evidence for the above guidelines has been rated as either low or moderate with many of the guidelines relying on expert opinion, the developers also conducted a literature review to supplement the KDOQI guidelines (literature reviewed through 2017).
- The reviewed articles offered 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 long-term catheters are associated with higher rates of infection and potentially mortality as well.
- The Committee noted that fistula remains the preferred access route for most dialysis patients over grafts and catheters.
    - The Committee expressed concern that the current fistula rate of 64% may be indicative that the remaining opportunities for improvement include many patients for whom fistula may not be the best route, such as those in hospice care, end-stage liver disease, or cancer.
    - The Committee expressed concern that the developer provided evidence based on updated guidelines from the National Kidney Foundation's (NKF) Kidney Disease Outcomes Quality Initiative (KDOQI), which included a downgrading of the evidence to support the measure to expert opinion.
    - It was noted that the developer supplemented the guidelines with literature that supported the measure focus.
- For performance gap, the Committee noted that, by the middle of 2017, 62.8% of prevalent hemodialysis patients were dialyzing with an AV fistula.
- For disparities, Hispanic ethnicity was associated with higher odds of fistula use whereas black communities are about 31% less likely to have fistulas than white ones.
- The Committee revoted on the measure during September 22, 2020 post-comment web meeting and did not recommend the measure for endorsement due to downgrading of evidence.

2. Scientific Acceptability of Measure Properties: <u>The measure meets the Scientific Acceptability criteria</u>

(2a. Reliability - precise specifications, testing; 2b. Validity - testing, threats to validity

2a. Reliability: **Yes-16; No-1**; 2b. Validity: **Yes-14; No-3**

<u>Rationale</u>:

- This measure was deemed complex and was evaluated by the NQF Scientific Methods Panel (SMP).
    - Vote for reliability – Moderate (H-4; M-5; L-0; I-0)
    - Vote for validity – Moderate (H-1; M-7; L-1; I-0)
- The Committee noted the score level reliability of the measure based on the IUR to be 0.755.
    - The developer also noted that their analyses produced a PIUR about 0.95 as well, though this was not included in the submission.
    - The Committee did not express any concerns related to the reliability.
- In the discussion on validity, the Committee noted the relationship between facility level quintiles of performance scores and the SMR and SHR using Poisson regression.
- The Committee noted that the risk adjustment is based on a multivariate logistic regression model.
    - The adjustment is made for age, BMI at incident, nursing home status, nephrologist's care prior to ESRD, duration of ESRD, diabetes as primary cause of ESRD, comorbidities, and two binary indicators including missing a CMS-2728 form and an indicator for if at least one of the comorbidities were present.
    - The common risk effects are assumed in order to improve computational stability in estimating facility-specific effects.
- The Committee noted 23% of data missingness and expressed a concern.
    - The developer noted that this is because the measure includes patients without Medicare coverage for whom comorbidities cannot be calculated, but they are included in the model to reduce bias.
    - The Committee considered the loss of information as a part of seeking balance in measuring an entire population and ensuring accuracy in the risk model and the presence of an adjustor in the model for those without comorbidity data.

2977 Hemodialysis Vascular Access: Standardized Fistula Rate
3. Feasibility: H-11; M-5; L-0; I-0 *(3a. Clinical data generated during care delivery; 3b. Electronic sources; 3c. Susceptibility to inaccuracies/ unintended consequences identified 3d. Data collection strategy can be implemented)* Rationale: • The Committee did not express any concerns related to feasibility, noting that all reviewers considered the feasibility to be high.
4. Use and Usability *4a. Use; 4a1. Accountability and transparency; 4a2. Feedback on the measure by those being measured and others; 4b. Usability; 4b1. Improvement; 4b2. The benefits to patients outweigh evidence of unintended negative consequences to patients)* 4a. Use: **Pass-16; No Pass-0** *4b. Usability:* **H-2; M-11; L-2; I-2** Rationale: • The Committee express concerns related to use, referencing its long use in federal accountability programs. • The Committee noted an unintended consequence of potentially limiting patient choice when they may prefer a catheter due to downward pressure on clinicians to achieve a high fistula rate.
5. Related and Competing Measures • No competing measures noted.
6. Standing Committee Recommendation for Endorsement: **Y-7**; **N-11** • The Standing Committee voted to not recommend the measure for endorsement at the post-comment web meeting on September 22, 2020. The measure failed on evidence—a must-pass criterion.
7. Public and Member Comment • Commenters suggested excluding from the denominator patients evaluated by vascular surgery but not eligible for arteriovenous fistula (AVF) due to either being a poor surgical candidate (e.g., having a lack of vessels amenable to fistula creation) and patients who refuse AVF creation. Since this measure did not reach consensus for the Evidence criterion, commenters encouraged NQF to consider the "Insufficient Evidence with Exception" pathway towards endorsement.
8. Consensus Standards Approval Committee (CSAC) Vote: Y-X; N-X (Month, Date, Year: [Endorsed or Not Endorsed])
9. Appeals

Appendix B: Renal Portfolio—Use in Federal Programs[a]

NQF #	Title	Federal Programs
0255	Measurement of Phosphorus Concentration	End-Stage Renal Disease Quality Incentive Program (implemented)
0256	Hemodialysis Vascular Access- Minimizing Use of Catheters as Chronic Dialysis Access	End-Stage Renal Disease Quality Incentive Program (implemented)
0257	Hemodialysis Vascular Access- Maximizing Placement of Arterial Venous Fistula (AVF)	End-Stage Renal Disease Quality Incentive Program (implemented)
0318	Peritoneal Dialysis Adequacy Clinical Performance Measure III - Delivered Dose of Peritoneal Dialysis Above Minimum	Dialysis Facility Compare (implemented) End-Stage Renal Disease Quality Incentive Program (considered)
0369	Dialysis Facility Risk-Adjusted Standardized Mortality Ratio	Dialysis Facility Compare (implemented) End-Stage Renal Disease Quality Incentive Program (considered)
1423	Minimum spKt/V for Pediatric Hemodialysis Patients	Dialysis Facility Compare (implemented)
1454	Proportion of Patients with Hypercalcemia	None
1463	Standardized Hospitalization Ratio for Admissions	Dialysis Facility Compare (implemented) End-Stage Renal Disease Quality Incentive Program (implemented)
1667	Pediatric Kidney Disease: ESRD Patients Receiving Dialysis: Hemoglobin Level < 10g/dL	Merit-Based Incentive Payment System (MIPS) (implemented)
2977	Hemodialysis Vascular Access: Standardized Fistula Rate	Dialysis Facility Compare (implemented) End-Stage Renal Disease Quality Incentive Program (finalized)
2978	Hemodialysis Vascular Access: Long-term Catheter Rate	End-Stage Renal Disease Quality Incentive Program (finalized)
2979	Standardized Transfusion Ratio for Dialysis Facilities	Dialysis Facility Compare (implemented) End-Stage Renal Disease Quality Incentive Program (implemented)
2988	Medication Reconciliation for Patients Receiving Care at Dialysis Facilities	End-Stage Renal Disease Quality Incentive Program (finalized)

[a] Per CMS Measures Inventory Tool as of 07/02/2020

Appendix C: Renal Standing Committee and NQF Staff

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Appendix D: Measure Specifications

	0369 Standardized Mortality Ratio for Dialysis Facilities
Steward	Centers for Medicare & Medicaid Services
Description	Standardized mortality ratio is defined to be the ratio of the number of deaths that occur for Medicare ESRD dialysis patients treated at a particular facility to the number of deaths that would be expected given the characteristics of the dialysis facility's patients and the national norm for dialysis facilities. This measure is calculated as a ratio but can also be expressed as a rate. When used for public reporting, the measure calculation will be restricted to facilities with greater than three expected deaths in the reporting year. This restriction is required to ensure patients cannot be identified due to small cell size.
Type	Outcome
Data Source	Claims, Registry Data. Data are derived from an extensive national ESRD patient database that 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. Information on hospitalizations is obtained from Part A Medicare Inpatient Claims Standard Analysis Files (SAFs), and past-year comorbidity data are obtained from multiple Part A types (inpatient, home health, hospice, skilled nursing facility claims) only.
Level	Facility
Setting	Other Dialysis Facility
Numerator Statement	Number of deaths among eligible patients at the facility during the time period.
Numerator Details	Information on death is obtained from several sources which include the CMS ESRD Program Medical Management Information System, the Death Notification Form (CMS Form 2746), and the Social Security Death Master File. The number of deaths that occurred among eligible dialysis patients during the time period is calculated. This count includes only Medicare patients as detailed below. It does not include deaths from street drugs or accidents unrelated to treatment as indicated on CMS form 2746 since these deaths are unlikely to have been due to treatment facility characteristics.
Denominator Statement	Number of deaths that would be expected among eligible dialysis patients at the facility during the time period, given the national average mortality rate and the patient mix at the facility.
Denominator Details	Assignment of Patients to Facilities We detail atient inclusion criteria, facility assignment, and how to count days at risk—all of which are required for the risk adjustment model. As patients can receive dialysis treatment at more than one facility in a given year, we assign each patient day to a facility (or no facility, in some cases) based on a set of conventions below.

	0369 Standardized Mortality Ratio for Dialysis Facilities
	General Inclusion Criteria for Dialysis Patients Since a patient's follow-up in the database can be incomplete during the first 90 days of ESRD therapy, we only include it into the tabulations after that patient has received chronic renal replacement therapy for at least 90 days. Thus, hospitalizations, mortality, and survival during the first 90 days of ESRD do not enter into the calculations. This minimum 90-day period also assures that most patients are eligible for Medicare, either as their primary or secondary insurer. It also excludes from analysis patients who die or recover renal function during the first 90 days of ESRD. In order to exclude patients who only received temporary dialysis therapy, we assign patients to a facility only after they have been on dialysis there for the past 60 days. This 60-day period is used both for patients who started ESRD for the first time and for those who returned to dialysis after a transplant.Deaths and survival during the first 60 days of dialysis at a facility do not affect the SMR of that facility. Identifying Facility Treatment Histories for Each Patient For each patient, we identify the dialysis provider at each point in time. Starting with day 91 after onset of ESRD, we attribute patients to facilities according to the following rules. A patient is attributed to a facility once the patient has been treated there for the past 60 days. When patients transfer from one facility to another, they continues to be attributed to the original facility for 60 days and then is attributed to the destination facility from day 61. In particular, patients are attributed to their current facility on day 91 of ESRD if that facility had treated them for the past 60 days. If on day 91, the facility had not treated a patient for the past 60 days, we wait until the patient reaches day 60 of continuous treatment at that facility before attributing the patient to that facility. When a patient is not treated in a single facility for a span of 60 days (for instance, if there were two switches within 60 days of each other), we do not attribute that patient to any facility. Patients were removed from a facility's analysis upon receiving a transplant. Patients who withdrew from dialysis or recovered renal function remain assigned to their treatment facility for 60 days after withdrawal or recovery. If a period of one year passes with neither paid dialysis claims nor CROWNWeb information to indicate that a patient was receiving dialysis treatment, we consider the patient lost to follow-up and do not include that patient in the analysis. If dialysis claims or other evidence of dialysis reappears, the patient is entered into analysis after 60 days of continuous therapy at a single facility. Days at Risk for Each Patient-Record After patient treatment histories are defined as described above, periods of follow-up time (or patient records) are created for each patient. A patient record begins each time the patient is determined to be at a different facility or at the start of each calendar year. Each patient record begins at 0 so that the number of days at risk always lies between 0 and 365 (or 366 for leap years). A patient who is in one facility for all four years gives rise to four patient records and is analyzed the same way as four separate patients in that facility for one year each. This measure is limited to Medicare dialysis patients who are either enrolled in Medicare Advantage or who reach a certain threshold of Medicare dialysis and inpatient claims. Specifically, months within a given dialysis patient period are used for SMR calculation when the patient is enrolled in Medicare Advantage or meets the criterion of being within two months after a month with either: (a) $1200+ of Medicare-paid dialysis claims OR (b) at least one Medicare inpatient claim. Then, we use the number of days at risk in each of these patient records to calculate the expected number of deaths for that record. We then sum the total number of expected deaths during all patient records at the facility as the expected number of deaths for that facility. Detailed methodology is described in the testing form.

	0369 Standardized Mortality Ratio for Dialysis Facilities
Exclusions	N/A
Exclusion details	N/A
Risk Adjustment	Statistical risk model
Stratification	N/A
Type Score	Ratio better quality = lower score
Algorithm	See flowchart in Appendix.
Copyright / Disclaimer	N/A

	2978 Hemodialysis Vascular Access: Long-term Catheter Rate
Steward	Centers for Medicare & Medicaid Services
Description	Percentage of adult hemodialysis patient-months using a catheter continuously for three months or longer for vascular access.
Type	Outcome: Intermediate Clinical Outcome
Data Source	Claims, Registry Data Data are derived from an extensive national ESRD patient database, which is primarily based on CROWNWeb facility-reported clinical and administrative data (including CMS-2728 Medical Evidence Form, CMS-2746 Death Notification Form, and CMS-2744 Annual Facility Survey Form and patient tracking data), the Renal Management Information System (REMIS), the Medicare Enrollment Database (EDB), and Medicare claims data. In addition, the database includes transplant data from the Scientific Registry of Transplant Recipients (SRTR), and data from the Nursing Home Minimum Dataset, the Quality Improvement Evaluation System (QIES) Business Intelligence Center (QBIC) (which includes Provider and Survey and Certification data from Automated Survey Processing Environment (ASPEN)), and the Dialysis Facility Compare (DFC). The database is comprehensive for Medicare patients not enrolled in Medicare Advantage. Medicare Advantage patients are included in all sources but their Medicare payment records are limited to inpatient claims. Non-Medicare patients are included in all sources except for the Medicare payment records. Tracking by dialysis provider and treatment modality is available for all patients including those with only partial or no Medicare coverage. CROWNWeb is the data source for establishing the vascular access type used to determine the numerator.
Level	Facility
Setting	Other Dialysis Facility
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.
Numerator Details	The number of patient-months with a long-term catheter in use. Long-term catheter use is defined as using a catheter, at the same facility, for at least three consecutive complete months as of the last day of the reporting month. Vascular access type for the measure is obtained from CROWNWeb only (representative of all ESRD dialysis patients). For a given month, if any of the following CROWNWeb “Access Type IDs” (16,18,19,20,21,”·”) has been recorded, a catheter is considered in use. If a catheter has been observed for three consecutive months (i.e., in the reporting month and the immediate two preceding months) at the same facility, the reporting month is counted in

	2978 Hemodialysis Vascular Access: Long-term Catheter Rate
	the numerator. Access Type ID "16" represents AV Fistula combined with a Catheter, "18" represents AV Graft combined with a Catheter, "19" represents Catheter only, "20" represents Port access only, "21" represents other/unknown, and "·" represents missing. If a patient changes dialysis facilities, the counting of the three consecutive complete months restarts at the new facility. We count patients with missing vascular access type in both the denominator and the numerator. Therefore missing vascular access type is counted as a catheter.
Denominator Statement	All patients at least 18 years old as of the first day of the reporting month who are determined to be maintenance hemodialysis patients (in-center and home HD) for the complete reporting month at the same facility. When used for public reporting, the measure calculation will be restricted to facilities with at least 11 patients in the reporting month. This restriction is required to ensure patients cannot be identified due to small cell size.
Denominator Details	For each patient, we identify the dialysis provider at each month using a combination of Medicare-paid dialysis claims, the Medical Evidence Form (Form CMS-2728), and data from CROWNWeb. These sources are used to identify patients that are receiving in-center or home hemodialysis for the entire reporting month. Patients are required to have been treated by the same facility for the complete month in order to be assigned to that facility for the reporting month. To be included in the denominator for a particular reporting month, the patient must be receiving home or in-center hemodialysis for the complete reporting month at the facility, and be at least 18 years old as of the first day of the month. The monthly patient count at a facility includes all eligible prevalent and incident patients. The number of patient-months over a time period is the sum of patients reported for the months covered by the time period. An individual patient may contribute up to 12 patient-months per year.
Exclusions	The following exclusions are implicit in the denominator definition: • Pediatric patients (<18 years old) • Patients on peritoneal dialysis • Patient-months on in-center or home hemodialysis for less than a complete reporting month at the same facility In addition, the following exclusions are applied to the denominator: • Patients with a catheter that have limited life expectancy: • Patients under hospice care in the current reporting month • Patients with metastatic cancer in the past 12 months • Patients with end-stage liver disease in the past 12 months • Patients with coma or anoxic brain injury in the past 12 months
Exclusion details	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

	2978 Hemodialysis Vascular Access: Long-term Catheter Rate
	with a Catheter, "18" represents AV Graft combined with a Catheter, "19" represents Catheter only, "20" represents Port access only, "21" represents other/unknown, and "." represents missing. Hospice status is determined from a separate CMS file that contains final action claims submitted by hospice providers. Once a beneficiary elects hospice, all hospice-related claims will be found in this file, regardless if the beneficiary is in Medicare fee-for-service or in a Medicare managed care plan. Patients are identified as receiving hospice care if they have any final action claims submitted to Medicare by hospice providers in the current month. If the patient did not have hospice claims in the preceding 12 months of hospice claims data, we assume this patient was not receiving hospice care in that reporting month. Diagnoses of metastatic cancer, end-stage liver disease, or coma in the past 12 months were determined from Medicare claim types. Medicare claims include inpatient hospitalizations, outpatient claims (including dialysis claims), and physician supplier claims. Claims from providers, such as laboratories that report diagnosis codes when testing for the presence of a condition, are excluded. A detailed list of ICD-10 diagnostic codes used to identify these comorbidities is included in the attached data dictionary code table (excel file). If the patient had missing comorbidity values in the preceding 12 months of Medicare claims, we assume this patient did not have the comorbidity in that reporting month.
Risk Adjustment	No risk adjustment or risk stratification
Stratification	N/A
Type Score	Rate/proportion better quality = lower score
Algorithm	See calculation flowchart in Appendix.
Copyright / Disclaimer	N/A

Appendix E: Related and Competing Measures

Comparison of NQF 0369, NQF 1463, and NQF 2496

0369: Standardized Mortality Ratio for Dialysis Facilities
1463: Standardized Hospitalization Ratio for Dialysis Facilities (SHR)
2496: Standardized Readmission Ratio (SRR) for dialysis facilities

Steward

0369: Standardized Mortality Ratio for Dialysis Facilities

Centers for Medicare & Medicaid Services

1463: Standardized Hospitalization Ratio for Dialysis Facilities (SHR)

Centers for Medicare & Medicaid Services

2496: Standardized Readmission Ratio (SRR) for dialysis facilities

Centers for Medicare & Medicaid Services

Description

0369: Standardized Mortality Ratio for Dialysis Facilities

Standardized mortality ratio is defined to be the ratio of the number of deaths that occur for Medicare ESRD dialysis patients treated at a particular facility to the number of deaths that would be expected given the characteristics of the dialysis facility's patients and the national norm for dialysis facilities. This measure is calculated as a ratio but can also be expressed as a rate.

1463: Standardized Hospitalization Ratio for Dialysis Facilities (SHR)

The standardized hospitalization ratio is defined to be the ratio of the number of hospital admissions that occur for Medicare ESRD dialysis patients treated at a particular facility to the number of hospitalizations that would be expected given the characteristics of the dialysis facility's patients and the national norm for dialysis facilities. This measure is calculated as a ratio but can also be expressed as a rate.

When used for public reporting, the measure calculation will be restricted to facilities with greater than five patient years at risk in the reporting year. This restriction is required to ensure patients cannot be identified due to small cell size.

2496: Standardized Readmission Ratio (SRR) for dialysis facilities

The Standardized Readmission Ratio (SRR) for a dialysis facility is the ratio of the number of observed index discharges from acute care hospitals to that facility that resulted in an unplanned readmission to an acute care hospital within 4-30 days of discharge to the expected number of readmissions given the discharging hospitals and the characteristics of the patients and based on a national norm. Note that the measure is based on Medicare-covered dialysis patients.

Type

0369: Standardized Mortality Ratio for Dialysis Facilities

Outcome

1463: Standardized Hospitalization Ratio for Dialysis Facilities (SHR)

Outcome

2496: Standardized Readmission Ratio (SRR) for dialysis facilities

Outcome

Data Source

0369: Standardized Mortality Ratio for Dialysis Facilities

Claims, Registry Data. Data are derived from an extensive national ESRD patient database that 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).

1463: Standardized Hospitalization Ratio for Dialysis Facilities (SHR)

Claims, Registry Data. Data are derived from an extensive national ESRD patient database that 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.

Information on hospitalizations is obtained from Part A Medicare Inpatient Claims Standard Analysis Files (SAFs), and past-year comorbidity data are obtained from multiple Part A types (inpatient, home health, hospice, skilled nursing facility claims) only.

No data collection instrument provided Attachment 1463_Code_List.xlsx

2496: Standardized Readmission Ratio (SRR) for dialysis facilities

Claims, Registry Data. 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.

Information on hospitalizations is obtained from Part A Medicare Inpatient Claims Standard Analysis Files (SAFs).

No data collection instrument provided

Attachment

2496_Data_Dictionary_Code_Table.xlsx

Level

0369: Standardized Mortality Ratio for Dialysis Facilities

When used for public reporting, the measure calculation will be restricted to facilities with greater than three expected deaths in the reporting year. This restriction is required to ensure patients cannot be identified due to small cell size.

1463: Standardized Hospitalization Ratio for Dialysis Facilities (SHR)

Facility

2496: Standardized Readmission Ratio (SRR) for dialysis facilities

Facility

Setting

0369: Standardized Mortality Ratio for Dialysis Facilities

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.

1463: Standardized Hospitalization Ratio for Dialysis Facilities (SHR)

Other Dialysis Facility

2496: Standardized Readmission Ratio (SRR) for dialysis facilities

Other Dialysis Facility

Numerator Statement

0369: Standardized Mortality Ratio for Dialysis Facilities

Information on hospitalizations obtained from Part A Medicare Inpatient Claims Standard Analysis Files (SAFs), and past-year comorbidity data obtained from multiple Part A types (inpatient, home health, hospice, skilled nursing facility claims) only.

1463: Standardized Hospitalization Ratio for Dialysis Facilities (SHR)

Number of inpatient hospital admissions among eligible patients at the facility during the reporting period.

2496: Standardized Readmission Ratio (SRR) for dialysis facilities

Each facility's observed number of hospital discharges that are followed by an unplanned hospital readmission within 4-30 days of discharge.

Numerator Details

0369: Standardized Mortality Ratio for Dialysis Facilities

No data collection instrument provided Attachment 0369_Code_List.xlsx

1463: Standardized Hospitalization Ratio for Dialysis Facilities (SHR)

The numerator is calculated through the use of Medicare claims data. When a claim is made for an inpatient hospitalization, the patient is identified and attributed to a dialysis facility following rules discussed below in the denominator details. The numerator is the count of all such hospitalizations over the reporting period.

2496: Standardized Readmission Ratio (SRR) for dialysis facilities

The numerator for a given facility is the total number of index hospital discharges that are followed by unplanned readmissions within 4-30 days of discharge and that are not preceded by a "planned" readmission or other competing event that also occurred within 4-30 days of discharge. Terms in this definition are described below.

A readmission is considered "planned" under two scenarios as outlined more completely in [1]:

i). The patient undergoes a procedure that is always considered planned (e.g., kidney transplant) or has a primary diagnosis that always indicates the hospitalization is planned (e.g., maintenance chemotherapy).

ii). The patient undergoes a procedure that MAY be considered planned if it is not accompanied by an acute diagnosis. For example, a hospitalization involving a heart valve procedure accompanied by a primary diagnosis of diabetes would be considered planned, whereas a hospitalization involving a heart valve procedure accompanied by a primary diagnosis of acute myocardial infarction (AMI) would be considered unplanned.

1. Centers for Medicare and Medicaid Services. 2018 All-Cause Hospital Wide Measure Updates and Specifications Report Hospital-Level 30-Day Risk-Standardized Readmission Measure – Version 7.0.

Other competing events include admissions to rehabilitation or psychiatric hospitals, death, transplant, loss to follow-up, withdrawal from dialysis, and recovery of renal function.

Denominator Statement

0369: Standardized Mortality Ratio for Dialysis Facilities

Facility

1463: Standardized Hospitalization Ratio for Dialysis Facilities (SHR)

Number of hospital admissions that would be expected among eligible patients at the facility during the reporting period given the patient mix at the facility.

2496: Standardized Readmission Ratio (SRR) for dialysis facilities

The denominator for a given facility is the expected number of observed index hospital discharges that result in an unplanned readmission in days 4-30 and that are not preceded by an unplanned or competing event. The expectation accounts for patient-level characteristics—including measures of patient comorbidities—and the discharging hospital, and is based on estimated readmission rates for an overall population norm that corresponds to an "average" facility.

Denominator Details

0369: Standardized Mortality Ratio for Dialysis Facilities

Other dialysis facility

1463: Standardized Hospitalization Ratio for Dialysis Facilities (SHR)

Assignment of Patients to Facilities

UM-KECC's treatment history file provides a complete history of the status, location, and dialysis treatment modality of an ESRD patient from the date of the first ESRD service until the patient dies or the data collection cutoff date is reached. For each patient, a new record is created each time he/she changes facility or treatment modality. Each record represents a time period associated with a specific modality and dialysis facility. CROWNWeb (including CMS Medical Evidence Form (Form CMS-2728), Death Notification Form (Form CMS-2746)) is the primary basis for placing patients at dialysis facilities, and dialysis claims are used as an additional source. Information regarding first ESRD service date, death and transplant is obtained from additional sources, including the CMS Enrollment Database (EDB), transplant data from the Organ Procurement and Transplant Network (OPTN), and the Social Security Death Master File.

As patients can receive dialysis treatment at more than one facility in a given year, we assign each patient day to a facility (or no facility, in some cases) based on a set of conventions described below, which largely align with those for the Standardized Mortality Ratio (SMR). We detail patient inclusion criteria, facility assignment, and how to count days at risk—all of which are required for the risk adjustment model.

General Inclusion Criteria for Dialysis Patients

Though a patient's follow-up in the database can be incomplete during the first 90 days of ESRD therapy, we only include a patient's follow-up in the tabulations after that patient has received chronic renal replacement therapy for at least 90 days. Thus, hospitalizations, mortality, and survival during the first 90 days of ESRD do not enter into the calculations. This minimum 90-day period also assures that most patients are eligible for Medicare, either as their primary or secondary insurer. It also excludes from analysis patients who die or recover renal function during the first 90 days of ESRD.

In order to exclude patients who only received temporary dialysis therapy at the facility, we assign patients to a facility only after they have been on dialysis there for the past 60 days. This 60-day period is used both for patients who started ESRD for the first time and for those who returned to dialysis after a transplant. Hospitalizations during the first 60 days of dialysis at a facility do not affect the SHR of that facility.

Identifying Facility Treatment Histories for Each Patient

For each patient, we identify the dialysis provider at each point in time. Starting with day 91 after the onset of ESRD, we attribute patients to facilities according to the following rules. A patient is attributed to a facility once the patient has been treated there for the

past 60 days. When a patient transfers from one facility to another, the patient continues to be attributed to the original facility for 60 days and then is attributed to the destination facility.

In particular, a patient is attributed to his or her current facility on day 91 of ESRD if that facility had treated him or her for the past 60 days. If on day 91, the facility had not treated a patient for the past 60 days, we wait until the patient reaches day 60 of continuous treatment before attributing the patient to that facility. When a patient is not treated in a single facility for a span of 60 days (for instance, if there were two switches within 60 days of each other), we do not attribute that patient to any facility. Patients are removed from facilities three days prior to transplant in order to exclude the transplant hospitalization. Patients who withdrew from dialysis or recovered renal function remain assigned to their treatment facility for 60 days after withdrawal or recovery.

If a period of one year passes with neither paid dialysis claims nor CROWNWeb information to indicate that a patient was receiving dialysis treatment, we consider the patient lost to follow-up and do not include that patient in the analysis. If dialysis claims, or other evidence of dialysis reappears, the patient is entered into analysis after 60 days of continuous therapy at a single facility.

Days at Risk for Medicare Dialysis Patients

After patient treatment histories are defined as described above, periods of follow-up in time since ESRD onset are created for each patient. In order to adjust for duration of ESRD appropriately, we define 6 time intervals with cut points at 6 months, 1 year, 2 years, 3 years, and 5 years. A new period begins each time the patient is determined to be at a different facility, or at the start of each calendar year or when crossing any of the above cut points.

In order to assure completeness of information on hospitalizations for all patients included in the analysis, we restrict to Medicare patients who are either enrolled in Medicare Advantage or who reach a certain threshold of Medicare dialysis and inpatient claims. Specifically, months within a given dialysis patient period are used for SHR calculation when the patient is enrolled in Medicare Advantage or meets the criterion of being within two months after a month with either: (a) $1200+ of Medicare-paid dialysis claims OR (b) at least one Medicare inpatient claim.

The number of days at risk in each of these patient-ESRD facility-year time periods is used to calculate the expected number of hospital admissions for the patient during that period. The SHR for a facility is the ratio of the total number of observed hospitalizations to the total number of expected hospitalizations during all time periods at the facility. Based on a risk adjustment model for the overall national hospitalization rates, we compute the expected number of hospitalizations that would occur for each month that each patient is attributed to a given facility. The sum of all such expectations for patients and months yields the overall number of hospital admissions that would be expected given the specific patient mix and forms the denominator of the measure.

The denominator of the SHR is derived from a proportional rates model (Lawless and Nadeau, 1995; Lin et al., 2000; Kalbfleisch and Prentice, 2002). This is the recurrent event analog of the well-known proportional hazards or Cox model (Cox, 1972; Kalbfleisch and Prentice, 2002). To accommodate large-scale data, we adopt a model with piecewise constant baseline rates (e.g. Cook and Lawless, 2007) and the computational methodology developed in Liu, Schaubel and Kalbfleisch (2012).

References:

Cook, R. and Lawless, J. The Statistical Analysis of Recurrent Events. New York: Springer. 2007.

Cox, D.R. (1972) Regression Models and Life Tables (with Discussion). J. Royal statistical Society, Series B, 34, 187-220.

Kalbfleisch, J.D. and Prentice, R. L. The Statistical Analysis of Failure Time Data. Wiley, New York, 2002.

Lawless, J. F. and Nadeau, C. Some simple and robust methods for the analysis of recurrent events, Technometrics, 37 1995, 355-364.

Lin, D.Y., Wei, L.J., Yang, I. and Ying, Z. Semi parametric regression for the mean and rate functions of recurrent events, Journal of the Royal Statistical Society Series B, 62, 2000, 771-730

2496: Standardized Readmission Ratio (SRR) for dialysis facilities

We use Medicare inpatient hospital claims to identify acute hospital discharges. All Medicare-covered live inpatient discharges of ESRD dialysis patients in a calendar year are considered eligible for this measure.

An index hospital discharge is a discharge from an acute care hospital that is not followed by a readmission whether planned or unplanned or by any competing event in the first three days following discharge.

Index discharges are attributed to the facility of record on the day of discharge for the patient. I f the patient transfers dialysis facilities at the time of hospital discharge, it is the new facility that is assigned the index discharge.

Expected Calculation: We calculate each dialysis facility's expected number of index hospital discharges during the one-year period that are followed by an unplanned readmission within 4-30 days of the discharge. The expected number is calculated by fitting a model with random effects for discharging hospitals, fixed effects for facilities, and regression adjustments for a set of patient-level characteristics. We compute the expectation for the given facility assuming readmission rates corresponding to an "average" facility with the same patient characteristics and same discharging hospitals as this facility. Model details are provided in the testing form.

Exclusions

0369: Standardized Mortality Ratio for Dialysis Facilities

Number of deaths among eligible patients at the facility during the time period.

1463: Standardized Hospitalization Ratio for Dialysis Facilities (SHR)

N/A

2496: Standardized Readmission Ratio (SRR) for dialysis facilities

Index Discharge Exclusions

Exclusion Details

0369: Standardized Mortality Ratio for Dialysis Facilities

Information on death is obtained from several sources, including the CMS ESRD Program Medical Management Information System, the Death Notification Form (CMS Form 2746), and the Social Security Death Master File. The number of deaths that occurred among eligible dialysis patients during the time period is calculated. This count includes only Medicare patients, as detailed below. It does not include deaths from street drugs or

accidents unrelated to treatment as indicated on CMS form 2746 since these deaths are unlikely to have been due to treatment facility characteristics.

1463: Standardized Hospitalization Ratio for Dialysis Facilities (SHR)

N/A

2496: Standardized Readmission Ratio (SRR) for dialysis facilities

A live inpatient hospital discharge is excluded if any of the following hold:

- Associated with a stay of 365 days or longer
- It is against medical advice
- It includes a primary diagnosis of cancer, mental health, or rehabilitation
- It Includes revenue center codes indicating rehabilitation
- It occurs after a patient's 12th hospital discharge in the calendar year
- It is from a PPS-exempt cancer hospital
- It is followed within 3 days by any hospitalization (at acute care, long-term care, rehabilitation, or psychiatric hospital or unit) or any other competing event (see S.5).

Risk Adjustment

0369: Standardized Mortality Ratio for Dialysis Facilities

Number of deaths that would be expected among eligible dialysis patients at the facility during the time period, given the national average mortality rate and the patient mix at the facility.

1463: Standardized Hospitalization Ratio for Dialysis Facilities (SHR)

Statistical risk model

2496: Standardized Readmission Ratio (SRR) for dialysis facilities

Statistical risk model

Stratification

0369: Standardized Mortality Ratio for Dialysis Facilities

Assignment of Patients to Facilities

1463: Standardized Hospitalization Ratio for Dialysis Facilities (SHR)

N/A

2496: Standardized Readmission Ratio (SRR) for dialysis facilities

N/A

Type Score

0369: Standardized Mortality Ratio for Dialysis Facilities

We detail patient inclusion criteria, facility assignment, and how to count days at risk—all of which are required for the risk adjustment model. As patients can receive dialysis treatment at more than one facility in a given year, we assign each patient day to a facility (or no facility, in some cases) based on a set of conventions below.

1463: Standardized Hospitalization Ratio for Dialysis Facilities (SHR)

Ratio better quality = lower score

2496: Standardized Readmission Ratio (SRR) for dialysis facilities

Ratio better quality = lower score

Algorithm

0369: Standardized Mortality Ratio for Dialysis Facilities

General Inclusion Criteria for Dialysis Patients

1463: Standardized Hospitalization Ratio for Dialysis Facilities (SHR)

See flowchart in appendix.

2496: Standardized Readmission Ratio (SRR) for dialysis facilities

See flowchart in appendix.

Submission items

0369: Standardized Mortality Ratio for Dialysis Facilities

Since a patient's follow-up in the database can be incomplete during the first 90 days of ESRD therapy, we only include it into the tabulations after that patient has received chronic renal replacement therapy for at least 90 days. Thus, hospitalizations, mortality, and survival during the first 90 days of ESRD do not enter into the calculations. This minimum 90-day period also assures that most patients are eligible for Medicare, either as their primary or secondary insurer. It also excludes from analysis patients who die or recover renal function during the first 90 days of ESRD.

1463: Standardized Hospitalization Ratio for Dialysis Facilities (SHR)

5.1 Identified measures:

#0369 *Standardized Mortality Ratio for Dialysis Facilities*

#2496 *Standardized Readmission Ratio (SRR) for dialysis facilities*

5a.1 Are specs completely harmonized? No

5a.2 If not completely harmonized, identify difference, rationale, impact: SHR is a related measure to the standardized mortality ratio (SMR) and the standardized readmission ration (SRR). SHR, SMR, and SRR are harmonized to the target population they measure (Medicare-covered ESRD patients), methods (SMR and SHR), and certain risk adjustment factors specific to the ESRD population, while each measure assesses different outcomes as reflected in their respective measure specifications.

SHR and SMR adjust for the same prevalent comorbidity risk factors, a similar set of patient characteristics, and use fixed effects in their modeling approach. The differences between SHR, SMR, and SRR reflect adjustment for factors specific to the outcome of each respective measure. Both SHR and SMR adjust for a set of prevalent comorbidities (observed in a prior year). However, the complete set of comorbidities differs for SRR. SRR excludes planned readmissions and adjusts for discharging hospitals, acknowledging that for readmission, hospitals also bear accountability for properly coordinating care with the dialysis facility. These risk adjustments in SRR account for those characteristics specifically associated with readmission, and do not apply to SHR or SMR. SHR, SRR, and SMR all include an adjustment for sex, while only SMR also adjusts for state death rates, race, and ethnicity.

5b.1 If competing, why superior or rationale for additive value: N/A

2496: Standardized Readmission Ratio (SRR) for dialysis facilities

5.1a.

#0369: *Standardized Mortality Ratio for Dialysis Facilities*

#1463 *Standardized Hospitalization Ratio for Dialysis Facilities (SHR)*

#1789 : *Hospital-Wide All-Cause Unplanned Readmission Measure (HWR)*

#2510 *Skilled Nursing Facility 30-Day All-Cause Readmission Measure (SNFRM)*

5a.1. No

5a.2. SRR is harmonized with the Standardized Hospitalization Ratio for Admissions (NQF #1463) and Standardized Mortality Ratio (NQF #0369) currently undergoing measure maintenance. The SRR applies to the same population—Medicare-covered ESRD patients—as SHR and SMR. SRR, SMR, and SHR include Medicare Advantage patients as they constitute a growing population of ESRD beneficiaries (approaching 20%). Both SRR and SHR include an indicator accounting for the proportion of Medicare Advantage coverage in order to minimize potential bias due to incomplete comorbidity ascertainment for Medicare Advantage (MA) patients. SRR, SHR, and SMR all restrict to inpatient claims for comorbidity risk adjustment and all measures adjust for a similar set of patient characteristics as the SRR and utilize fixed effects in their modeling approach.

However, SRR adjusts for a different set of comorbidities that are associated with a high risk of readmission. There are several NQF-endorsed measures that share the same focus with SRR but target different patient populations and/or care settings. The proposed SRR has the same measure focus—unplanned 30-day readmissions—as CMS' Hospital-Wide All-Cause Readmission Rate (NQF #1789), and the Skilled Nursing Facility 30-Day All-Cause Readmission Measure (SNF; NQF #2510). SRR is harmonized with both the HWR and SNF measures in restricting to the use of inpatient Medicare claims for comorbidity risk adjustment and exclusion of planned readmissions. There are several differences between the SRR and the existing CMS, HWR, and SNF measures. Some of the differences are intended to account for unique features of the ESRD chronic dialysis population.

Inclusion/Exclusion

1) SRR includes patients with incomplete claims history from the prior year. We do this to allow capture of incident ESRD patients that may not have a complete year of Medicare coverage

2) SRR includes Medicare Advantage patients (approaching 20% of ESRD dialysis patients) while HWR and SNF are restricted to Medicare FFS patients with Part A only

3) Only SRR excludes discharges that follow a patient's 12th admission in the year

4) SRR excludes from the numerator planned readmissions that include a diagnosis of "fluid and electrolyte disorders" (CCS 55) that meet other criteria for planned readmissions (see Appendix).

Risk Adjustment

1) SRR does not adjust for comorbidities that are highly prevalent in the ESRD population, such as acute renal failure, dialysis status, kidney transplant, fluid/electrolyte disorders, and iron deficiency

2) SRR additionally adjusts for diagnoses (grouped by the Clinical Classification Software (CCS) method) that are relatively rare but have a high risk of 30-day readmission in the ESRD population

3) SRR adjusts for length of hospital stay, diabetes as the primary cause of ESRD, time on dialysis, and sex

4) Only SRR includes an indicator for Medicare Advantage coverage at time of index discharge

(5) SRR adjusts for comorbidities identified during the index hospitalization which were not present on admission whereas HWR does not.

Additional differences between the SRR and SNF

1) the SNF includes a different target population (though we recognize a notable proportion of ESRD dialysis patients reside in nursing homes)

2) SNF includes readmissions within 1-day of discharge while SRR excludes readmissions within 3 days of discharge.

5b.1. N/A

Comparison of NQF 2978, NQF 2594, and NQF 0256

2978: Hemodialysis Vascular Access: Long-term Catheter Rate

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

0256: Minimizing Use of Catheters as Chronic Dialysis Access

Steward

2978: Hemodialysis Vascular Access: Long-term Catheter Rate

Centers for Medicare & Medicaid Services

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

The Permanente Federation

0256: Minimizing Use of Catheters as Chronic Dialysis Access

Centers for Medicare & Medicaid Services

Description

2978: Hemodialysis Vascular Access: Long-term Catheter Rate

Percentage of adult hemodialysis patient-months using a catheter continuously for three months or longer for vascular access.

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

Optimal End-Stage Renal Disease (ESRD) Starts is the percentage of new adult ESRD patients during the measurement period who experience a planned start of renal replacement therapy by receiving a preemptive kidney transplant, by initiating home dialysis, or by initiating outpatient in-center hemodialysis via arteriovenous fistula or arteriovenous graft.

0256: Minimizing Use of Catheters as Chronic Dialysis Access

Percentage of patient-months on maintenance hemodialysis during the last HD treatment of month with a chronic catheter continuously for 90 days or longer prior to the last hemodialysis session.

Type

2978: Hemodialysis Vascular Access: Long-term Catheter Rate

Outcome: Intermediate Clinical Outcome

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

Process

0256: Minimizing Use of Catheters as Chronic Dialysis Access

Outcome

Data Source

2978: Hemodialysis Vascular Access: Long-term Catheter Rate

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

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

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

No data collection instrument provided Attachment 2978_Data_Dictionary_Code_Table.xlsx

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

Claims, Electronic Health Records, Other, Registry Data

The data collection instrument is in the appendix. It can be completed from records maintained by the renal care team as patients reach ESRD and submitted to the measure analyst every six months.

CMS 2728 Form: Within KP, we do not have access to this data, but all the essential data elements are available on the CMS 2728 Form which is submitted for every new ESRD patient in the US (whether they have Medicare coverage or not). The only missing data is the date of stopping dialysis if recover from acute renal failure by 90 days, and in most cases, a 2728 Form is not submitted for these patients. Patients who recover kidney function and stop dialysis by 90 days are not included in the denominator or numerator. We anticipate that this will be the source of data for organizations outside of KP in the future.

Available in attached appendix at A.1

Attachment NQF_Renal_Measure_2594_Data_Elements.xlsx

0256: Minimizing Use of Catheters as Chronic Dialysis Access

Claims, Electronic Health Records CROWNWeb is the primary data source. However, this measure can be collected through Medicare claims data (since July 2010) and Fistula First

Breakthrough Initiative data (though the definition of the measure is slightly different). The measure has been publicly reported using claims data since 2013.

No data collection instrument provided No data dictionary

Level

2978: Hemodialysis Vascular Access: Long-term Catheter Rate

Facility

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

Clinician : Group/Practice, Health Plan, Integrated Delivery System, Population : Regional and State

0256: Minimizing Use of Catheters as Chronic Dialysis Access

Facility

Setting

2978: Hemodialysis Vascular Access: Long-term Catheter Rate

Other Dialysis Facility

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

Outpatient Services

0256: Minimizing Use of Catheters as Chronic Dialysis Access

Post-Acute Care

Numerator Statement

2978: Hemodialysis Vascular Access: Long-term Catheter Rate

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.

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

The number of new ESRD patients age 18 and over who initiate renal replacement therapy in the twelve month measurement period with an optimal ESRD therapy (specific optimal ESRD therapies are defined in section S.6).

0256: Minimizing Use of Catheters as Chronic Dialysis Access

Number of patient-months in the denominator who were continuously using a chronic catheter as hemodialysis access for 90 days or longer prior to the last hemodialysis session during the month.

Numerator Details

2978: Hemodialysis Vascular Access: Long-term Catheter Rate

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

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

For a given month, if any of the following CROWNWeb “Access Type IDs” (16,18,19,20,21,”·”) has been recorded, a catheter is considered in use. If a catheter has

been observed for three consecutive months (i.e., in the reporting month and the immediate two preceding months) at the same facility, the reporting month is counted in the numerator. Access Type ID “16” represents AV fistula combined with a catheter, “18” represents AV graft combined with a catheter, “19” represents catheter only, “20” represents port access only, “21” represents other/unknown, and “·” represents missing. If a patient changes dialysis facilities, the counting of the three consecutive complete months restarts at the new facility.

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

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

The Optimal ESRD Starts numerator is the total number of new patients age 18 and over who initiate renal replacement therapy for the first time and do not come off dialysis by 90 days, with one of the following:

• A preemptive kidney transplant or simultaneous pancreas-kidney transplant (SPK). Preemptive means that the patient has never experienced outpatient dialysis, OR

• Initial home or self-dialysis modality, including planned and "successful urgent start" peritoneal dialysis (PD) and home hemodialysis (HHD) via an arteriovenous fistula or arteriovenous graft. ”Successful urgent start” peritoneal dialysis means that the patient never experienced outpatient hemodialysis via a hemodialysis catheter before starting outpatient peritoneal dialysis, OR

• Initial outpatient hemodialysis (HD), including self-hemodialysis (SHD), via arteriovenous fistula (AVF) prepared surgically without use of artificial materials. The patient may have a hemodialysis catheter in place if it is not used. Do not count patients with a single needle in AVF with blood return via catheter, OR

• Initial outpatient hemodialysis (HD), including self-hemodialysis (SHD), via arteriovenous graft (AVG), limited to no more than 10% of all patients starting in-center hemodialysis#. The patient may have a hemodialysis catheter if it is not used. Do not count patients with a single needle in AVG with blood return via catheter.

An arteriovenous fistula (AVF) is highly preferred for hemodialysis over an arteriovenous graft (AVG). AVFs are associated with many fewer follow-up encounters with vascular surgery and interventional radiology to remove clots, dilate and replace. CMS has recognized AVF superiority in its Fistula First Quality Initiative, which continues to collect data and promote practice improvement methods.

Nevertheless, not every patient is suitable for an AVF, and these patients require an AVG for hemodialysis, which is still much better than hemodialysis by catheter. In our 3-year experience measuring Optimal ESRD Starts in Kaiser Permanente, less than 5% of new hemodialysis patients start with an AVG as their initial access. The 10% of new hemodialysis patient limit for AVG was determined by an interregional Kaiser Permanente nephrologist work group to be consistent with the CMS Fistula First Initiative and in consideration of potential practice changes in the future.

0256: Minimizing Use of Catheters as Chronic Dialysis Access

The numerator will be determined by counting the patient-months in the denominator who were on maintenance hemodialysis with a chronic catheter continuously for 90 days or longer prior to the last hemodialysis session of the month.

Denominator Statement

2978: Hemodialysis Vascular Access: Long-term Catheter Rate

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

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

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

The number of patients age 18 and over who receive a preemptive kidney transplant or initiate long-term dialysis therapy (do not recover kidney function by 90 days) for the first time in the 12-month measurement period.

0256: Minimizing Use of Catheters as Chronic Dialysis Access

Adult hemodialysis patients who have had ESRD for greater than 90 days as of of the first day of the reporting month.

Denominator Details

2978: Hemodialysis Vascular Access: Long-term Catheter Rate

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

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

The population being measured are patients age 18 and over who 1) receive a preemptive kidney transplant (having never received outpatient dialysis), including simultaneous pancreas and kidney transplant, plus 2) patients age 18 and over initiating long-term maintenance dialysis who do not recover kidney function by 90 days.

The population includes patients who start renal replacement therapy and then are lost to follow up (lose insurance, move away) and/or die.

The denominator is the number of the above patients within the measured entity during the 12-month measurement period.

Clarifications based on the above definition (not exclusions):

1. The denominator does not include patients who initiate outpatient dialysis but then recover GFR to the point where they can stop dialysis treatments by 90 days after the first outpatient dialysis.

2. The denominator does not include patients who previously reached ESRD, such as

• Patients who previously were on dialysis 90 days or more who then recovered kidney function for a while, but then restarted dialysis

• Patients who switch from one dialysis modality to another, for example switching from in-center hemodialysis to home dialysis.

• Patients with failing kidney transplants starting or returning to dialysis.

3. The denominator does not include patients who died without experiencing outpatient dialysis or a kidney transplant.

0256: Minimizing Use of Catheters as Chronic Dialysis Access

The patient's age will be determined by subtracting the patient's date of birth from the first day of the reporting month.

Hemodialysis patients are defined as follows: "Admit Date" to the specified facility is prior or equal to the first day of the study period, AND the patient has not been discharged ("Discharge Date" is null or blank), OR "Discharge Date" from the facility is greater than or equal to the last day of the study period AND "Treatment Dialysis Broad Start Date" is prior or equal to the first day of the study period, AND "Dialysis Broad Type of Treatment" = 'HD', AND "Primary Dialysis Setting" ='Dialysis Facility/Center' or 'Home' on the last day of the study period, AND "Date Regular Chronic Dialysis Began" is prior to the first day of the study period.

For both CROWNWeb and Claims data, the denominator will include all hemodialysis patients who are at least 18 years old and have had ESRD for greater than 90 days as of the first day of the reporting month.

Exclusions

2978: Hemodialysis Vascular Access: Long-term Catheter Rate

The following exclusions are implicit in the denominator definition:

• Pediatric patients (<18 years old)

• Patients on peritoneal dialysis

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

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

• Patients with a catheter that have limited life expectancy:

• Patients under hospice care in the current reporting month

• Patients with metastatic cancer in the past 12 months

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

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

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

None

0256: Minimizing Use of Catheters as Chronic Dialysis Access

Exclusions that are implicit in the denominator definition include pediatric patients (<18 years old), and acute hemodialysis patients (hemodialysis patients who have had ESRD for less than 91 days). There are no additional exclusions for this measure.

Exclusion Details

2978: Hemodialysis Vascular Access: Long-term Catheter Rate

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

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

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

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

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

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

None

0256: Minimizing Use of Catheters as Chronic Dialysis Access

See above denominator details.

Risk Adjustment

2978: Hemodialysis Vascular Access: Long-term Catheter Rate

No risk adjustment or risk stratification

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

No risk adjustment or risk stratification

0256: Minimizing Use of Catheters as Chronic Dialysis Access

No risk adjustment or risk stratification

Stratification

2978: Hemodialysis Vascular Access: Long-term Catheter Rate

N/A

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

As there is no patient sampling (all patients who reach ESRD are included), there is no stratified sampling.

For comparative purposes and tracking within Kaiser Permanente, the metric has been calculated (stratified) by geographic medical regions or areas. Results by geographic regions/areas are shown in the appendix.

0256: Minimizing Use of Catheters as Chronic Dialysis Access

N/A

Type Score

2978: Hemodialysis Vascular Access: Long-term Catheter Rate

Rate/proportion better quality = lower score

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

Rate/proportion

better quality = higher score

0256: Minimizing Use of Catheters as Chronic Dialysis Access

Rate/proportion better quality = lower score

Algorithm

2978: Hemodialysis Vascular Access: Long-term Catheter Rate

See calculation flowchart in Appendix.

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

1. The target population is all new ESRD patients as described in S.9. Denominator Details. There are no exclusions. Data is compiled and submitted on standardized spreadsheets.

2. Determine denominator:

• Eliminate patients who do not meet denominator definition S.9. Denominator Details

a. Eliminate patients who recovered kidney function by day 90

b. Eliminate patients who previously were on dialysis 90 days or more who then recovered kidney function then later restarted dialysis

c. Eliminate patients starting dialysis after failed transplant

d. Eliminate patients changing dialysis modality

e. Eliminate patients who died without experiencing outpatient dialysis or a kidney transplant

• Eliminate patients with incomplete data if unavailable

3. Count patients in each category. Each denominator patient must be assigned to one and only one of the groups below. Rules are listed in S.6. Numerator Details

Group A: Preemptive kidney transplant

Group B: Peritoneal Dialysis (Home)

Group C: Home Hemodialysis

Group D: In-center HD with AVF

Group E: In-center HD with AVG

Group F: In-center HD with Catheter

4. Note: Denominator = A + B + C + D + E + F
5. Calculate Adjusted AVG (E') = Smaller of [E] or [(C + D + E + F) ÷ 10]
6. Calculate Optimal ESRD Starts = ((A + B + C + D + E'))/Denominator) x 100%
7. Calculate Modality Sub-metrics

- Preemptive Kidney Transplant Starts + (A/Denominator) x 100%
- Home Dialysis Starts = ((B + C))/Denominator) x 100%
- Optimal AVF & AVG Starts = ((D + E'))/Denominator) x 100%
- Non-Optimal ESRD Starts = 100% - Optimal ESRD Starts

0256: Minimizing Use of Catheters as Chronic Dialysis Access

For this measure calculation, the numerator will be divided by the denominator. Calculation of the numerator and denominator is described below.

The denominator will include all patients at least 18 years old who are determined to be maintenance hemodialysis patients.

The patient's age will be determined by subtracting the patient's date of birth from the first day of the reporting month.

Hemodialysis patients are defined as follows: "Admit Date" to the specified facility is prior or equal to the first day of the study period, AND the patient has not been discharged ("Discharge Date" is null or blank), OR "Discharge Date" from the facility is greater than or equal to the last day of the study period AND "Treatment Dialysis Broad Start Date" is prior or equal to the first day of the study period, AND "Dialysis Broad Type of Treatment" = 'HD', AND "Primary Dialysis Setting" ='Dialysis Facility/Center' or 'Home' on the last day of the study period, AND "Date Regular Chronic Dialysis Began" is prior to the first day of the study period.

The numerator will be determined by counting the patient-months in the denominator who were on maintenance hemodialysis with a chronic catheter continuously for 90 days or longer prior to the last hemodialysis session of the month.

For CROWNWeb data, the numerator is defined as "Access_Type_id" in (19,20) while "19" means catheter only and "20" means port access only AND "Date Access Type for Dialysis Changed" is blank or, if populated, is more than 90 days prior to the last hemodialysis session of the month.

For claims data, we use data prior to reporting period, a 90-day lookback period (e.g. October -December 2012 for January 2013 reporting period) to determine catheter history AND vascular access type should satisfy (vas_cat='Y' and art_graft=' ' and art_fistula=' ')).
For this measure calculation, the numerator will be divided by the denominator. Calculation of the numerator and denominator is described below.

The denominator will include all patients at least 18 years old who are determined to be maintenance hemodialysis patients.

The patient's age will be determined by subtracting the patient's date of birth from the first day of the reporting month.

Hemodialysis patients are defined as follows: “Admit Date” to the specified facility is prior or equal to the first day of the study period, AND the patient has not been discharged (“Discharge Date” is null or blank), OR “Discharge Date” from the facility is greater than or equal to the last day of the study period AND “Treatment Dialysis Broad Start Date” is prior or equal to the first day of the study period, AND “Dialysis Broad Type of Treatment” = ‘HD’, AND “Primary Dialysis Setting” =‘Dialysis Facility/Center’ or ‘Home’ on the last day of the study period, AND “Date Regular Chronic Dialysis Began” is prior to the first day of the study period.

The numerator will be determined by counting the patient-months in the denominator who were on maintenance hemodialysis with a chronic catheter continuously for 90 days or longer prior to the last hemodialysis session of the month.

For CROWNWeb data, the numerator is defined as “Access_Type_id” in (19,20) while “19” means catheter only and “20” means port access only AND “Date Access Type for Dialysis Changed” is blank or, if populated, is more than 90 days prior to the last hemodialysis session of the month.

For Claims data, we use data prior to reporting period, a 90 day lookback period (e.g. October-December 2012 for January 2013 reporting period) to determine catheter history AND vascular access type should satisfy (vas_cat='Y' and art_graft=' ' and art_fistula=' ')).

Submission items

2978: Hemodialysis Vascular Access: Long-term Catheter Rate

5.1 Identified measures:

#2594 *Optimal End-Stage Renal Disease (ESRD) Starts*

5a.1 Are specs completely harmonized? No

5a.2 If not completely harmonized, identify difference, rationale, impact: Measure #2594 is not a dialysis facility level measure. The setting focus addresses a different provider type which falls outside the purview of measures evaluating dialysis facility performance on fistula use. This suggests a fundamental difference in the measure target populations, setting and intent that cannot be harmonized. Additionally, the measure is limited to incident patients, while the LTC measure includes both incident and prevalent patients as the measured population.

5b.1 If competing, why superior or rationale for additive value: There are no competing measures.

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

5.1 Identified measures:

#0256 *Minimizing Use of Catheters as Chronic Dialysis Access*

#0257 *Maximizing Placement of Arterial Venous Fistula (AVF)*

#1460 *Bloodstream Infection in Hemodialysis Outpatients*

5a.1 Are specs completely harmonized?

No

5a.2 If not completely harmonized, identify difference, rationale, impact: There are two related measures, #0256 and# 0257, but no competing measures. These measures and Optimal ESRD Starts are complementary with different rationales and different data collection methods. Optimal ESRD Starts focuses on patients who need to start renal replacement therapy, including hemodialysis, whereas #0256 and #0257 both focus on

improving vascular access for patients already on hemodialysis. The Measure #0256 *Hemodialysis Vascular Access – Minimizing use of catheters as Chronic Dialysis Access* metric is a percentage of patients currently on maintenance hemodialysis with a chronic catheter in place continuously for 90 days or more. As opposed to Optimal ESRD Starts, which is an incidence rate for new ESRD patients, measure #0256 is a prevalence measure of the existing hemodialysis population.

Another difference is that even a single first treatment with a catheter is a negative Optimal ESRD Start outcome, whereas measure #0256 requires a catheter to be present for 90 days or longer. While the denominator populations are not harmonized, Optimal ESRD Starts is complimentary as more Optimal ESRD Start without a hemodialysis catheter will lower chronic catheter prevalence. The Measure #0257 *Hemodialysis Vascular Access – Maximizing Placement of Arterial Venous Fistula* metric is a percentage of patients on maintenance hemodialysis using an autogenous arteriovenous fistula (AVF). Like optimal ESRD Starts, it focuses on increasing the use of arteriovenous fistulas as the best type of vascular access for hemodialysis. As opposed to Optimal ESRD Starts, which is an incidence rate for new ESRD patients, measure #0257 is a prevalence measure of the existing hemodialysis population. While the denominator populations are not harmonized, Optimal ESRD Starts is complimentary. An Optimal ESRD Start with an AVF will result in higher AVF prevalence. In summary, Optimal ESRD starts is quite different in focus (pre-ESRD patient planning versus managing patients already on hemodialysis), covers home dialysis and transplant as well as inpatient hemodialysis, and is the only metric to impact patients before and as they transition to ESRD. It is an incidence rate at the point of reaching ESRD as opposed to a prevalence rate in patients already on hemodialysis. Optimal ESRD Starts tells how a healthcare entity is performing in the build up to ESRD to optimize each patient's modality choice, and the other two measures address how an organization is doing after patients reach ESRD—limited only to hemodialysis.

0256: Minimizing Use of Catheters as Chronic Dialysis Access

5.1 Identified measures:

5a.1 Are specs completely harmonized?

5a.2 If not completely harmonized, identify difference, rationale, impact:

5b.1 If competing, why superior or rationale for additive value:

Comparison of NQF 2978, NQF 0257, and NQF 2977

2978: Hemodialysis Vascular Access: Long-term Catheter Rate
0257: Maximizing Placement of Arterial Venous Fistula (AVF)
2977: Hemodialysis Vascular Access: Standardized Fistula Rate

Steward

2978: Hemodialysis Vascular Access: Long-term Catheter Rate

Centers for Medicare & Medicaid Services

0257: Maximizing Placement of Arterial Venous Fistula (AVF)

Centers for Medicare & Medicaid Services

2977: Hemodialysis Vascular Access: Standardized Fistula Rate

Centers for Medicare & Medicaid Services

Description

2978: Hemodialysis Vascular Access: Long-term Catheter Rate

Percentage of adult hemodialysis patient-months using a catheter continuously for three months or longer for vascular access.

0257: Maximizing Placement of Arterial Venous Fistula (AVF)

Percentage of patient-months for patients on maintenance hemodialysis during the last HD treatment of month using an autogenous AV fistula.

2977: Hemodialysis Vascular Access: Standardized Fistula Rate

Adjusted percentage of adult hemodialysis patient-months using an autogenous arteriovenous fistula (AVF) as the sole means of vascular access.

Type

2978: Hemodialysis Vascular Access: Long-term Catheter Rate

Outcome: Intermediate Clinical Outcome

0257: Maximizing Placement of Arterial Venous Fistula (AVF)

Outcome

2977: Hemodialysis Vascular Access: Standardized Fistula Rate

Outcome: Intermediate Clinical Outcome

Data Source

2978: Hemodialysis Vascular Access: Long-term Catheter Rate

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

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

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

No data collection instrument provided Attachment 2978_Data_Dictionary_Code_Table.xlsx

0257: Maximizing Placement of Arterial Venous Fistula (AVF)

Claims, Electronic Health Records

This measure is primarily designed for collection in CROWNWeb but can also be calculated from Fistula First and Medicare claims data. The measure has been publicly reported using Medicare claims data since 2013.

No data collection instrument provided No data dictionary

2977: Hemodialysis Vascular Access: Standardized Fistula Rate

Claims, Registry Data. 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.

No data collection instrument provided Attachment 2977_Data_Dictionary_Code_Table.xlsx

Level

2978: Hemodialysis Vascular Access: Long-term Catheter Rate

Facility

0257: Maximizing Placement of Arterial Venous Fistula (AVF)

Facility

2977: Hemodialysis Vascular Access: Standardized Fistula Rate

Facility

Setting

2978: Hemodialysis Vascular Access: Long-term Catheter Rate

Other Dialysis Facility

0257: Maximizing Placement of Arterial Venous Fistula (AVF)

Post-Acute Care

2977: Hemodialysis Vascular Access: Standardized Fistula Rate

Other Dialysis Facility

Numerator Statement

2978: Hemodialysis Vascular Access: Long-term Catheter Rate

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.

0257: Maximizing Placement of Arterial Venous Fistula (AVF)

The numerator is the number of patient-months in the denominator who were using an autogenous AV fistula at the last HD treatment of month.

2977: Hemodialysis Vascular Access: Standardized Fistula Rate

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.

Numerator Details

2978: Hemodialysis Vascular Access: Long-term Catheter Rate

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

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

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

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

0257: Maximizing Placement of Arterial Venous Fistula (AVF)

The numerator will be determined by counting the patient-months in the denominator who were using an AV fistula as the means of access.

2977: Hemodialysis Vascular Access: Standardized Fistula Rate

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.

Denominator Statement

2978: Hemodialysis Vascular Access: Long-term Catheter Rate

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

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

0257: Maximizing Placement of Arterial Venous Fistula (AVF)

For both CROWNWeb and Claims data, the denominator will include all hemodialysis patients who are at least 18 years old and have had ESRD for greater than 90 days as of the first day of the reporting month.

2977: Hemodialysis Vascular Access: Standardized Fistula Rate

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.

Denominator Details

2978: Hemodialysis Vascular Access: Long-term Catheter Rate

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

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

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

0257: Maximizing Placement of Arterial Venous Fistula (AVF)

For both CROWNWeb and Claims data, the denominator will include all hemodialysis patients who are at least 18 years old and have had ESRD for at least 90 days as of the first day of the reporting month.

2977: Hemodialysis Vascular Access: Standardized Fistula Rate

For each patient, we identify the dialysis provider at each month using a combination of data from CROWNWeb, Medicare-paid dialysis claims, and 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.

Exclusions

2978: Hemodialysis Vascular Access: Long-term Catheter Rate

The following exclusions are implicit in the denominator definition:

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

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

Patients with a catheter that have limited life expectancy:

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

0257: Maximizing Placement of Arterial Venous Fistula (AVF)

Exclusions that are implicit in the denominator definition include pediatric patients (<18 years old) and acute hemodialysis patients (hemodialysis patients who have had ESRDS for less than 91 days). There are no additional exclusions for this measure.

2977: Hemodialysis Vascular Access: Standardized Fistula Rate

The following exclusions are implicit in the denominator definition:

- 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

Exclusion Details

2978: Hemodialysis Vascular Access: Long-term Catheter Rate

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

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

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

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

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

0257: Maximizing Placement of Arterial Venous Fistula (AVF)

N/A

2977: Hemodialysis Vascular Access: Standardized Fistula Rate

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).

Risk Adjustment

2978: Hemodialysis Vascular Access: Long-term Catheter Rate

No risk adjustment or risk stratification

0257: Maximizing Placement of Arterial Venous Fistula (AVF)

No risk adjustment or risk stratification

2977: Hemodialysis Vascular Access: Standardized Fistula Rate

Statistical risk model

Stratification

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N/A

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N/A

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N/A

Type Score

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Rate/proportion better quality = lower score

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Rate/proportion better quality = higher score

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Rate/proportion better quality = higher score

Algorithm

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See calculation flowchart in Appendix. 139029

0257: Maximizing Placement of Arterial Venous Fistula (AVF)

For this measure calculation, the numerator will be divided by the denominator.

Calculation of the numerator and denominator is described below.

The denominator will include all patients at least 18 years old who are determined to be maintenance hemodialysis patients.

The patient's age will be determined by subtracting the patient's date of birth from the first day of the reporting month.

Hemodialysis patients are defined as follows: "Admit Date" to the specified facility is prior or equal to the first day of the study period, AND the patient has not been discharged ("Discharge Date" is null or blank), OR "Discharge Date" from the facility is greater than or equal to the last day of the study period AND "Treatment Dialysis Broad Start Date" is prior or equal to the first day of the study period, AND "Dialysis Broad Type of Treatment" = 'HD', AND "Primary Dialysis Setting" ='Dialysis Facility/Center' or 'Home' on the last day of the study period, AND "Date Regular Chronic Dialysis Began" is prior to the first day of the study period. The denominator will include all patients greater than or equal to 18 years old who are determined to be in-center hemodialysis, or home hemodialysis patients.

The numerator will be determined by counting the patient-months in the denominator who were on maintenance hemodialysis using an AV fistula as the means of access.

In CROWNWeb, a patient is counted in the numerator if "Access_type_id" in (14,16) at the last treatment of the month where "14" represents AV fistula only (with 2 needles) and "16" represents AV fistula combined with a catheter; while in Medical Claims data, a patient is included if (vas_cat=' ' and art_graft=' ' and art_fistula='Y') OR (vas_cat='Y' and art_graft=' ' and art_fistula='Y') at the last treatment of the month. For this measure calculation, the numerator will be divided by the denominator.

Calculation of the numerator and denominator is described below.

The denominator will include all patients at least 18 years old who are determined to be maintenance hemodialysis patients.

The patient's age will be determined by subtracting the patient's date of birth from the first day of the reporting month.

Hemodialysis patients are defined as follows: "Admit Date" to the specified facility is prior or equal to the first day of the study period, AND the patient has not been discharged ("Discharge Date" is null or blank), OR "Discharge Date" from the facility is greater than or equal to the last day of the study period AND "Treatment Dialysis Broad Start Date" is prior or equal to the first day of the study period, AND "Dialysis Broad Type of Treatment" = 'HD', AND "Primary Dialysis Setting" ='Dialysis Facility/Center' or 'Home' on the last day of the study period, AND "Date Regular Chronic Dialysis Began" is prior to the first day of the study period. The denominator will include all patients greater than or equal to 18 years old who are determined to be in-center hemodialysis or home hemodialysis patients.

The numerator will be determined by counting the patient-months in the denominator who were on maintenance hemodialysis using an AV fistula as the means of access.

In CROWNWeb, a patient is counted in the numerator if "Access_type_id" in (14,16) at the last treatment of the month where "14" represents AV fistula only (with 2 needles) and "16" represents AV fistula combined with a catheter; while in Medical Claims data, a patient is included if (vas_cat=' ' and art_graft=' ' and art_fistula='Y') OR (vas_cat='Y' and art_graft=' ' and art_fistula='Y') at the last treatment of the month.

2977: Hemodialysis Vascular Access: Standardized Fistula Rate

See calculation flowchart in Appendix. 139029

Submission items

2978: Hemodialysis Vascular Access: Long-term Catheter Rate

5.1 Identified measures:

#2594 *Optimal End-Stage Renal Disease (ESRD) Starts*

5a.1 Are specs completely harmonized? No

5a.2 If not completely harmonized, identify difference, rationale, impact:

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

5b.1 If competing, why superior or rationale for additive value: There are no competing measures.

0257: Maximizing Placement of Arterial Venous Fistula (AVF)

5.1 Identified measures:

5a.1 Are specs completely harmonized?

5a.2 If not completely harmonized, identify difference, rationale, impact:

5b.1 If competing, why superior or rationale for additive value:

2977: Hemodialysis Vascular Access: Standardized Fistula Rate

5.1 Identified measures:

#2594 *Optimal End-Stage Renal Disease (ESRD) Starts*

5a.1 Are specs completely harmonized? No

5a.2 If not completely harmonized, identify difference, rationale, impact:

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.1 If competing, why superior or rationale for additive value: There are no competing measures.

Appendix F: Pre-Evaluation Comments

No pre-evaluation comments received as of June 5, 2020.

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