NATIONAL QUALITY FORUM

Measure Information

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

Brief Measure Information

NQF #: 1463
Corresponding Measures:
De.2. **Measure Title:** Standardized Hospitalization Ratio for Dialysis Facilities (SHR)
Co.1.1. **Measure Steward:** Centers for Medicare & Medicaid Services
De.3. **Brief Description of Measure:** 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 less than 5 patient years at risk in the reporting year. This restriction is required to ensure patients cannot be identified due to small cell size.
1b.1. **Developer Rationale:** Hospitalizations are an important indicator of patient morbidity and quality of life. On average, dialysis patients are admitted to the hospital nearly twice a year and spend an average of 11.2 days in the hospital per year [1]. Hospitalizations account for approximately 33% percent of total Medicare expenditures for ESRD patients [1]. Studies have shown that improved health care delivery and care coordination may help reduce unplanned acute care including hospitalization [1]. Hospitalization rates vary across dialysis facilities even after adjustment for patient characteristics, suggesting that hospitalizations might be influenced by dialysis facility practices. An adjusted facility-level standardized hospitalization ratio, accounting for differences in patients' characteristics, plays an important role in identifying potential problems and helps facilities provide cost-effective quality health care to help limit escalating medical costs.

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

S.4. **Numerator Statement:** Number of inpatient hospital admissions among eligible patients at the facility during the reporting period.
S.6. **Denominator Statement:** 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.
S.8. **Denominator Exclusions:** N/A

De.1. **Measure Type:** Outcome
S.17. **Data Source:** Claims, Registry Data
S.20. **Level of Analysis:** Facility

IF Endorsement Maintenance – Original Endorsement Date: Aug 16, 2011 **Most Recent Endorsement Date:** Dec 08, 2016

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

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

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

1. Evidence, Performance Gap, Priority Importance to Measure and Report

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

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

1463_Evidence.docx

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

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

Yes

1b. Performance Gap

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

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

1b.1. **Briefly explain the rationale for this measure** *(e.g., how the measure will improve the quality of care, the benefits or improvements in quality envisioned by use of this measure)*
If a COMPOSITE (e.g., combination of component measure scores, all-or-none, any-or-none), SKIP this question and answer the composite questions.

Hospitalizations are an important indicator of patient morbidity and quality of life. On average, dialysis patients are admitted to the hospital nearly twice a year and spend an average of 11.2 days in the hospital per year [1]. Hospitalizations account for approximately 33% percent of total Medicare expenditures for ESRD patients [1]. Studies have shown that improved health care delivery and care coordination may help reduce unplanned acute care including hospitalization [1].

Hospitalization rates vary across dialysis facilities even after adjustment for patient characteristics, suggesting that hospitalizations might be influenced by dialysis facility practices. An adjusted facility-level standardized hospitalization ratio, accounting for differences in patients' characteristics, plays an important role in identifying potential problems and helps facilities provide cost-effective quality health care to help limit escalating medical costs.

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

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

Standardized hospitalization ratios (SHR) vary widely across facilities each year 2015-2018. For 2018, the SHR varied from 0 to 3.55. The mean value was 0.99 and the standard deviation (SD) was 0.25. The data used to calculate these rates is limited to those facilities with at least 5 patient years at risk (reflecting how the measure is currently calculated on DFC).

Distribution of the SHR, 2015-2018:

2015: Facilities = 6339, Mean SHR = .98, SD = .26, 10th = .67, 25th = .81, 50th = .96, 75th = 1.13, 90th = 1.31

2016: Facilities = 6520, Mean SHR = .99, SD = .26, 10th = .68, 25th = .82, 50th = .97, 75th = 1.13, 90th = 1.30

2017: Facilities = 6783, Mean SHR = .99, SD = .25, 10th = .69, 25th = .83, 50th = .97, 75th = 1.13, 90th = 1.29

2018: Facilities = 7041, Mean SHR = .99, SD = .25, 10th = .69, 25th = .82, 50th = .98, 75th = 1.14, 90th = 1.30

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

N/A

1b.4. **Provide disparities data from the measure as specified (current and over time) by population group, e.g., by race/ethnicity, gender, age, insurance status, socioeconomic status, and/or disability.** *(This is required for maintenance of endorsement. Describe the data source including number of measured entities; number of patients; dates of data; if a sample, characteristics of the entities included.) For measures that show high levels of performance, i.e., "topped out", disparities data may demonstrate an opportunity for improvement/gap in care for certain sub-populations. This information also will be used to address the sub-criterion on improvement (4b1) under Usability and Use.*

Race and ethnicity have been shown to be predictors of hospitalization. Using data from 2015-2018, we observed that black, Native American and Asian/Pacific Islander patients had lower risk of hospitalization (HRs=0.93, 0.97 and 0.81, respectively) compared to white patients. Hispanic and patients of unknown ethnicity had lower risk of hospitalization (both HRs = 0.90) compared to non-Hispanic patients. Female patients had a higher risk of hospitalization than male patients (HR=1.53). Further, patients unemployed at the onset of ESRD had a higher risk of hospitalization (HR=1.12) than patients that were employed; Medicare dual eligible patients had a higher risk of hospitalization (HR=1.06) than Medicare Primary patients. Area Deprivation Index had virtually no impact on risk of hospitalization (HR=1.001).

Refer to Risk Adjustment section (2b3) for further analyses on race, ethnicity, sex and socioeconomic status.

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

N/A

2. Reliability and Validity Scientific Acceptability of Measure Properties

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

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

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

Renal, Renal : End Stage Renal Disease (ESRD)

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

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

Populations at Risk

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

N/A

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

This is not an eMeasure **Attachment:**

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

Attachment **Attachment:** 1463_Code_List.xlsx

S.2c. Is this an instrument-based measure (i.e., data collected via instruments, surveys, tools, questionnaires, scales,

etc.)? Attach copy of instrument if available.
No, this is not an instrument-based measure **Attachment:**

S.2d. Is this an instrument-based measure (i.e., data collected via instruments, surveys, tools, questionnaires, scales, etc.)? Attach copy of instrument if available.
Not an instrument-based measure

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

S.3.2. **For maintenance of endorsement,** please briefly describe any important changes to the measure specifications since last measure update and explain the reasons.
This form is being used for endorsement maintenance. Updates include:
• Prevalent Comorbidity Adjustment:
o Grouped 210 individual ICD-9 prevalent comorbidities into 90 condition groups, derived from the AHRQ CCS groups.
o Limited source of prevalent comorbidities to inpatient claims. The switch to using only Medicare inpatient claims to identify prevalent comorbidities is due to the lack of Medicare outpatient claims data for the growing Medicare Advantage (MA) patient population. By using the original set of Medicare claims datasets (inpatient, outpatient, hospice, skilled nursing, and home health), MA patient prevalent comorbidities would be systematically biased as they would only be populated by Medicare inpatient claims compared to non-MA patient prevalent comorbidities that would be populated by the aforementioned set of Medicare claim sources.

• Include all time at risk for Medicare Advantage patients, and added a Medicare Advantage indicator for adjustment in the model.

• Updates to parameterization of existing adjustment factors and re-evaluation of interactions
• A patient's time spent in a skilled nursing facility may play a role in increased risk of hospitalization, as nursing home residence is a marker of higher morbidity. UM-KECC has leveraged information from the Medicare Minimum Dataset (MDS) regarding a patient's time spent in a nursing home to create three distinct groups to use in the SHR model. The three groups are those patients who have spent 0, 1-89 (short term), or 90 or more (long term) days in the nursing home in the previous 365 days.

S.4. **Numerator Statement** *(Brief, narrative description of the measure focus or what is being measured about the target population, i.e., cases from the target population with the target process, condition, event, or outcome) DO NOT include the rationale for the measure.*
IF an OUTCOME MEASURE, state the outcome being measured. Calculation of the risk-adjusted outcome should be described in the calculation algorithm (S.14).
Number of inpatient hospital admissions among eligible patients at the facility during the reporting period.

S.5. **Numerator Details** *(All information required to identify and calculate the cases from the target population with the target process, condition, event, or outcome such as definitions, time period for data collection, specific data collection items/responses, code/value sets – Note: lists of individual codes with descriptors that exceed 1 page should be provided in an Excel or csv file in required format at S.2b)*
IF an OUTCOME MEASURE, describe how the observed outcome is identified/counted. Calculation of the risk-adjusted outcome should be described in the calculation algorithm (S.14).
The numerator is calculated through 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.

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

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

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

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. That is, 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 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 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 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 time 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

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

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

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

S.11. **Risk Adjustment Type** (Select type. Provide specifications for risk stratification in measure testing attachment)
Statistical risk model
If other:

S.12. **Type of score:**
Ratio
If other:

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

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

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

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

S.16. **Survey/Patient-reported data** *(If measure is based on a survey or instrument, provide instructions for data collection and guidance on minimum response rate.)*
Specify calculation of response rates to be reported with performance measure results.
N/A

S.17. **Data Source** *(Check ONLY the sources for which the measure is SPECIFIED AND TESTED).*
If other, please describe in S.18.
Claims, Registry Data

S.18. **Data Source or Collection Instrument** *(Identify the specific data source/data collection instrument (e.g. name of database, clinical registry, collection instrument, etc., and describe how data are collected.)*
IF instrument-based, identify the specific instrument(s) and standard methods, modes, and languages of administration.
Data are derived from an extensive national ESRD patient database 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.

S.19. **Data Source or Collection Instrument** *(available at measure-specific Web page URL identified in S.1 OR in attached appendix at A.1)*
No data collection instrument provided

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

S.21. **Care Setting** *(Check ONLY the settings for which the measure is SPECIFIED AND TESTED)*
Other
If other: Dialysis Facility

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

2. Validity – See attached Measure Testing Submission Form
1463_testing_form.docx

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

2.2 For maintenance of endorsement

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

Yes

2.3 For maintenance of endorsement

Risk adjustment: For outcome, resource use, cost, and some process measures, risk-adjustment that includes social risk factors is not prohibited at present. Please update sections 1.8, 2a2, 2b1,2b4.3 and 2b5 in the Testing attachment and S.140 and S.11 in the online submission form. NOTE: These sections must be updated even if social risk factors are not included in the risk-adjustment strategy. You MUST use the most current version of the Testing Attachment (v7.1) -- older versions of the form will not have all required questions.

Yes - Updated information is included

3. Feasibility

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

3a. Byproduct of Care Processes

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

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

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

If other:

3b. Electronic Sources

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

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

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

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

N/A

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

Attachment:

3c. Data Collection Strategy

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

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

IF instrument-based, consider implications for both individuals providing data (patients, service recipients, respondents) and those whose performance is being measured.
Data collection is accomplished via Medicare Claims and CROWNWeb, a web-based and electronic batch submission platform maintained and operated by CMS contractors. Measures reported on DFC are reviewed on a regular basis by dialysis facility providers. Review of comments and questions received in the past for the SHR showed only rare instances of concern expressed about inaccurate or missing data.

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

4. Usability and Use

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

4a. Accountability and Transparency

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

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

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

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

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

Public Reporting: Dialysis Facility Compare (DFC)

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

Geographic area: United States

Number of accountable entities: All Medicare-certified dialysis facilities that are eligible for the measure, and have at least 5 patient years at risk. For the most recent DFC report, that was 6,911 facilities.

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

ESRD Quality Incentive Program (ESRD QIP):
Purpose: The ESRD QIP will reduce payments to ESRD facilities that do not meet or exceed certain performance standards. The measure was added to the program for PY2020

Geographic area: United States

Number of accountable entities: All Medicare-certified dialysis facilities that are eligible for the measure, and have at least 5 patient years at risk. For the most recent QIP release (PY 2020), that was 6913 facilities.

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

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

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

4a2.1.1. **Describe how performance results, data, and assistance with interpretation have been provided to those being measured or other users during development or implementation.**
How many and which types of measured entities and/or others were included? If only a sample of measured entities were included, describe the full population and how the sample was selected.
Results of this measure are currently reported on Dialysis Facility Compare, and in the ESRD Quality Incentive Program. All Medicare-certified dialysis facilities are eligible for reporting in both programs (approximately 7,000 dialysis facilities). Each program has a helpdesk and supporting documentation available to assist with interpretation of the measure results.

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

4a2.1.2. **Describe the process(es) involved, including when/how often results were provided, what data were provided, what educational/explanatory efforts were made, etc.**
For DFC, the results are first reported to facilities via a closed preview period, where facilities can review their data prior to each of the quarterly updates of the public Dialysis Facility Compare website. These preview reports are posted on dialysisdata.org, where facilities can also find a detailed Guide to the Quarterly Dialysis Facility Compare Reports and other supporting documentation. Facilities can submit comments/questions about their results at any time, and can request patient lists for their facilities during the specified preview periods.

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

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

4a2.2.1. **Summarize the feedback on measure performance and implementation from the measured entities and others described in 4d.1.**
Describe how feedback was obtained.
For DFC, feedback can be provided any time through contacting the dialysisdata.org helpdesk. Preview periods allow for specific times for facilities review and comment on measure calculations, and provide an opportunity to request a patient list.

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

4a2.2.2. **Summarize the feedback obtained from those being measured.**
DFC: DFC: Comments received during DFC preview periods tend to be technical nature, asking for clarification on how the SHR is calculated for particular facilities, including questions about patient assignment and application of exclusion and risk adjustment criteria, and counting of readmissions in both the SHR and SRR resulting in potentially penalizing facilities in both measures.

QIP: Note that since UM-KECC is not the contractor responsible for the ESRD Quality Incentive Program, we do not have access to the detailed comments/requested that are submitted during the annual preview period for that program.

4a2.2.3. **Summarize the feedback obtained from other users**
QIP: Since the SHR was first proposed in the PY 2020 proposed rule, commenters raised issues related to whether the outcome of the measure (hospitalizations) was attributable to the dialysis facility. The concern was lack of exclusions for those hospitalizations that were not related to dialysis treatment or attributable to care provided by the dialysis facility.

4a2.3. **Describe how the feedback described in 4a2.2.1 has been considered when developing or revising the measure specifications or implementation, including whether the measure was modified and why or why not.**
While we have made revisions to the measure specifications during this maintenance cycle, we have not made changes directly in response to feedback provided through the public reporting programs. We address those issues directly below.

• Several comments questioned the use of both SHR and SRR which could doubly penalize facilities since a readmission would count in both the SHR and SRR measures. While the SHR and SRR may both count the same hospitalization event, we believe this is appropriate because it places additional emphasis on the importance of avoiding hospitalizations and re-hospitalization for dialysis patients. Doing so can help reduce this major cost driver as well as promote better patient health related quality of life. In addition, while the SRR and SHR are moderately correlated with one another, it is possible for a facility to score relatively well on one measure, and relatively poorly on the other. We also believe that the measures capture distinct aspects of the quality of care provided by a dialysis facility. The SRR assesses the coordination of care transitions as dialysis patients are discharged from an acute care hospital into the care of a dialysis facility, and the SHR evaluates the facility's overall performance in reducing hospitalizations.
• Several comments were suggestions for more expansive risk adjustment, facility attribution, and a cause-specific SHR. The SHR under maintenance has and continues to include risk adjustment for a set of prevalent comorbidities that were determined likely not to be the result of facility care (as determined by a 2015 Technical Expert Panel). The SHR also excludes patients from a facility if they have not had ESRD for more than 90 days, or if they have not been receiving treatment at the facility for more than 60 days, which precludes the risk of patients being included in a facility's SHR prior to treatment. The 2006 SHR TEP was not able to achieve consensus on a cause-specific SHR and therefore recommended the all-cause measure. The SHR measure continues to be an all-cause hospitalization measure, reflecting hospital admissions regardless of cause. This is consistent in approach to other NQF-endorsed measures, such as the SRR (NQF #2496).

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

4b1. **Refer to data provided in 1b but do not repeat here. Discuss any progress on improvement (trends in performance results, number and percentage of people receiving high-quality healthcare; Geographic area and number and percentage of accountable entities and patients included.)**
If no improvement was demonstrated, what are the reasons? If not in use for performance improvement at the time of initial endorsement, provide a credible rationale that describes how the performance results could be used to further the goal of high-quality, efficient healthcare for individuals or populations.
Hospitalization rates have decreased since 2015 as evidenced by the negative coefficients for calendar year from the SHR model. The hospitalization rate for 2016 decreased by 2.7% compared to 2015 (p-value <0.0001). Subsequent years had a larger decrease in the hospitalization rate compared to 2015 at 6.8% lower for 2017 and about 5.7% lower for 2018 (p-value<0.0001 for both) compared to 2015. While the rate increased slightly for 2018 compared to 2017, this is likely due to random variation.

SHR Calendar Year Model Coefficients, 2015-2018

2015: the reference year
2016: Coefficient = -0.027, P-value = <0.0001
2017: Coefficient = -0.068, P-value = <0.0001
2018: Coefficient = -0.057, P-value = <0.0001

4b2. Unintended Consequences

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

4b2.1. **Please explain any unexpected findings (positive or negative) during implementation of this measure including unintended impacts on patients.**
None

4b2.2. **Please explain any unexpected benefits from implementation of this measure.**
None

5. Comparison to Related or Competing Measures

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

5. Relation to Other NQF-endorsed Measures

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

5.1a. **List of related or competing measures (selected from NQF-endorsed measures)**
0369 : Standardized Mortality Ratio for Dialysis Facilities
2496 : Standardized Readmission Ratio (SRR) for dialysis facilities

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

5a. Harmonization of Related Measures

The measure specifications are harmonized with related measures;
OR
The differences in specifications are justified

5a.1. **If this measure conceptually addresses EITHER the same measure focus OR the same target population as NQF-endorsed measure(s):**
Are the measure specifications harmonized to the extent possible?
No

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

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

5b.1. **If this measure conceptually addresses both the same measure focus and the same target population as NQF-endorsed measure(s):**
Describe why this measure is superior to competing measures (e.g., a more valid or efficient way to measure quality); OR provide a rationale for the additive value of endorsing an additional measure. (Provide analyses when possible.)
N/A

Appendix

A.1 Supplemental materials may be provided in an appendix. All supplemental materials (such as data collection instrument or methodology reports) should be organized in one file with a table of contents or bookmarks. If material pertains to a specific submission form number, that should be indicated. Requested information should be provided in the submission form and required attachments. There is no guarantee that supplemental materials will be reviewed.
Attachment **Attachment:** 1463_Flow_Chart.pdf

Contact Information

Co.1 **Measure Steward (Intellectual Property Owner):** Centers for Medicare & Medicaid Services
Co.2 **Point of Contact:** Kimberly, Rawlings
Co.3 **Measure Developer if different from Measure Steward:** University of Michigan Kidney Epidemiology and Cost Center
Co.4 **Point of Contact:** Casey, Parrotte, parrotte@med.umich.edu

Additional Information

Ad.1 **Workgroup/Expert Panel involved in measure development**
Provide a list of sponsoring organizations and workgroup/panel members' names and organizations. Describe the members' role in measure development.
The following is a list of TEP members who participated in the End-Stage Renal Disease Evaluation of Potential Prevalent Comorbidity Adjustments in the Standardized Hospitalization Ratio (SHR) and the Standardized Mortality Ratio (SMR) TEP. In this advisory role, the primary duty of the TEP was to review any existing measures in terms of comorbidities included as adjusters, and determine if there was sufficient evidence to support the inclusion of specific proposed comorbidities as measure adjusters, and relatedly, suggest measure specifications.

Caroline Steward, APRN, CCRN, CNN
Advanced Practice Nurse (Hemodialysis)
Capital Health System
Trenton, NJ

Dana Miskulin, MD, MS
Staff Nephrologist
Turfts Medical Center
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Associate Professor of Medicine
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Roberta Wager, MSN, RN
Renal Care Coordinator
Fresenius Medical Care
Member of Forum of ESRD Networks Beneficiary Council
Forum of ESRD Networks
Boerne, TX

Danielle Ward
Member of Forum of ESRD Networks Beneficiary Council
Forum of ESRD Networks
Board Member
Network 6
Wake Forest, NC

Measure Developer/Steward Updates and Ongoing Maintenance
Ad.2 **Year the measure was first released:**
Ad.3 **Month and Year of most recent revision:** 04, 2020
Ad.4 **What is your frequency for review/update of this measure?** Annually
Ad.5 **When is the next scheduled review/update for this measure?** 04, 2021

Ad.6 **Copyright statement:**
Ad.7 **Disclaimers:**

Ad.8 **Additional Information/Comments:**

NATIONAL QUALITY FORUM—Evidence (subcriterion 1a)

Measure Number (*if previously endorsed*)**:** 1463
Measure Title: Standardized Hospitalization Ratio for Dialysis Facilities
IF the measure is a component in a composite performance measure, provide the title of the Composite Measure here: Click here to enter composite measure #/ title
Date of Submission: 4/9/2020

1a.1.This is a measure of: (*should be consistent with type of measure entered in De.1*)
Outcome
☒ Outcome: Hospitalization
☐ Patient-reported outcome (PRO): Click here to name the PRO
PROs include HRQoL/functional status, symptom/symptom burden, experience with care, health-related behaviors. (*A PRO-based performance measure is not a survey instrument. Data may be collected using a survey instrument to construct a PRO measure.)*
☐ Intermediate clinical outcome (*e.g., lab value*): Click here to name the intermediate outcome
☐ Process: Click here to name what is being measured
☐ Appropriate use measure: Click here to name what is being measured
☐ Structure: Click here to name the structure
☐ Composite: Click here to name what is being measured

1a.2 LOGIC MODEL Diagram or briefly describe the steps between the healthcare structures and processes (e.g., interventions, or services) and the patient's health outcome(s). The relationships in the diagram should be easily understood by general, non-technical audiences. Indicate the structure, process or outcome being measured.

2011 Submission

Hospitalization rates are an important indicator of patient morbidity and quality of life. On average, dialysis patients are admitted to the hospital twice a year and hospitalizations account for approximately 36 percent of total Medicare expenditures for dialysis patients (U.S. Renal Data System, 2007). Measures of the frequency of hospitalization help efforts to control escalating medical costs, and play an important role in providing cost-effective health care.

2016 Submission:

There are numerous dialysis facility processes of care that can influence the risk of unplanned patient hospitalization. Key among these are:

(1) 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 the need for hospitalization.
(2) Inadequate infection prevention. Inadequate infection prevention processes, including suboptimal management of vascular access, can lead to bacteremia or septicemia, increasing the possibility of the need for hospitalization.
(3) Inadequate dialysis. Failure to maintain processes to ensure adequate dialysis can lead to low Kt/v, increasing the possibility of the need for hospitalization.

2019/2020 Submission: no change to the previous submission

1a.3 Value and Meaningfulness: **IF** this measure is derived from patient report, provide evidence that the target population values the measured ***outcome, process, or structure*** and finds it meaningful. (Describe how and from whom their input was obtained.)

****RESPOND TO ONLY ONE SECTION BELOW -EITHER 1a.2, 1a.3 or 1a.4) ****

1a.2 FOR OUTCOME MEASURES including PATIENT REPORTED OUTCOMES - Provide empirical data demonstrating the relationship between the outcome (or PRO) to at least one healthcare structure, process, intervention, or service.

2011 Submission

This was not a question on the 2011 Submission Form.

2016 Submission:

Hospitalization rates remain very high in US chronic dialysis patients relative to the general population, despite a nearly 20% decline from 2005-2013. This trend in lower hospitalization is in contrast to the relatively stable hospitalization rates for the US general population over the same time period, suggesting that dialysis providers have been somewhat successful in reducing unnecessary hospitalizations through quality of care improvements.

According to the 2015 USRDS Annual Report, approximately ½ of all dialysis patient hospitalizations continue to be caused by cardiovascular or infectious causes over that time period [1]. Recent research points to many additional opportunities to further reduce unnecessary hospitalization in this population.

Programs developed to impact dialysis provider practices have been shown to improve intermediate outcomes (reduced catheter vascular access, small solute adequacy, anemia management) and mortality, modality options, infection prevention, and dialysis organization culture [2-19]. These practice improvements have been linked to reduced hospitalizations in this population. For example, one study examined dialysis provider interventions targeting incident patients in order to improve outcomes for these patients that are at particularly high risk for poor outcomes that can lead to higher morbidity and mortality [2]. The results suggested improved clinical outcomes in terms of the percentage of incident patients having a preferred vascular access type. In turn this has the potential to reduce hospitalization risk, along with mortality; other work on vascular access type also supports the link between access type and hospitalization, specifically due to chronic catheter use [3].

2019/2020 Submission:

Hospitalization rates remain very high in US chronic dialysis patients relative to the general population, despite an overall 15% decline from 2007-2016 [1]. In recent years the trend in lower hospitalization among this population has stabilized, suggesting that dialysis providers have been somewhat successful in reducing unnecessary hospitalizations through quality of care improvements.

As of the 2018 USRDS Annual Report, in 2015-2016 approximately just under half of all dialysis patient hospitalizations continue to be caused by cardiovascular causes and infections (any type) [1].

Earlier research highlighted opportunities to further reduce unnecessary hospitalization in this population. Programs developed to impact dialysis provider practices have been shown to improve intermediate outcomes (reduced catheter vascular access, small solute adequacy, anemia management). Infection prevention practices and dialysis organization culture [2-19] have also been shown to reduce the risk of unplanned hospitalization. For example, one study examined dialysis provider interventions targeting incident patients in order to improve outcomes for these patients that are at particularly high risk for poor outcomes that can lead to higher morbidity and mortality [2]. The results suggested improved clinical outcomes in terms of the percentage of incident patients having a preferred vascular access type. In turn this has the potential to reduce hospitalization risk, along with mortality; other studies have reported an association between hospitalization and long-term catheter use [3].

More recent studies have provided further support for additional opportunities available to dialysis facilities to further reduce hospitalizations. Achieving adequate small solute clearance, as measured by Kt/V, continues to be a cornerstone of care with a favorable impact on the risk of hospitalization [25, 29]. More specifically, the components of the dialysis prescription such as the calcium [33] and sodium concentrations [27] also impact overall hospitalization risk. Additionally, how staff at dialysis facilities manage a patient's potassium balance, whether through nutritional counseling or the dialysate potassium, can impact hospitalization rates particularly over the long interdialytic interval [26].

One area that has received increased attention has been maintaining appropriate fluid balance as it relates to hospitalizations for fluid overload. Studies have evaluated efforts to reduce missed treatments [21], achieve written target weight [23], and evaluation of the target weight after hospitalization [22] and all highlight the importance of volume management to reduce hospitalizations.

Finally, the CMS Centers for Medicare and Medicaid Innovation's Comprehensive End Stage Renal Disease Care model emphasizes care coordination as a central feature of care delivery in order to reduce utilization and improve outcomes. This is evidenced by reported reductions in hospitalizations overall compared to the baseline year [34].

References – all submissions, with more recent studies noted in red

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

[2] Wilson SM, Robertson JA, Chen G, Goel P, Benner DA, Krishnan M, Mayne TJ, Nissenson AR. The IMPACT (Incident Management of Patients, Actions Centered on Treatment) Program: A Quality Improvement Approach for Caring for Patients Initiating Long-term Hemodialysis. Am J Kidney Dis 60(3): 435-443, 2012

BACKGROUND: Patients beginning dialysis therapy are at risk of death and illness. The IMPACT (Incident Management of Patients, Actions Centered on Treatment) quality improvement program was developed to improve incident hemodialysis patient outcomes through standardized care.

STUDY DESIGN: Quality improvement report.

SETTING & PARTICIPANTS: Patients who started hemodialysis therapy between September 2007 and December 2008 at DaVita facilities using the IMPACT program (n = 1,212) constituted the intervention group. Propensity score-matched patients who initiated hemodialysis therapy in the same interval at DaVita facilities not using the IMPACT program (n = 2,424) made up the control group.

QUALITY IMPROVEMENT PLAN: IMPACT intervention included a structured intake process and monitoring reports; patient enrollment in a 90-day patient education program and 90-day patient management pathway.

OUTCOMES: Mean dialysis adequacy (Kt/V), hemoglobin and albumin levels, percentage of patients using preferred vascular access (arteriovenous fistula or graft), and mortality at each quarter.

RESULTS: Compared with the non-IMPACT group, the IMPACT group was associated with a higher proportion of patients dialyzing with a preferred access at 90 days (0.50 [95% CI, 0.47-0.53] vs 0.47 [95% CI, 0.45-0.49]; P = 0.1) and 360 days (0.63 [95% CI, 0.61-0.66] vs 0.48 [95% CI, 0.46-0.50]; P < 0.001) and a lower mortality rate at 90 days (24.8 [95% CI, 19.0-30.7] vs 31.9 [95% CI, 27.1-36.6] deaths/100 patient-years; P = 0.08) and 360 days (17.8 [95% CI, 15.2-20.4] vs 25.1 [95% CI, 20.7-25.2] deaths/100 patient-years; P = 0.01).

LIMITATIONS: The study does not determine the care processes responsible for the improved outcomes.

CONCLUSIONS: Intense management of incident dialysis patients with the IMPACT quality improvement program was associated with significantly decreased first-year mortality. Focused attention to the care of incident patients is an important part of a dialysis program.

[3] Vassalotti JA, Jennings WC, Beathard GA, Neumann M, Caponi S, Fox CH, Spergel LM and the Fistula First Breakthrough Initiative Community Education Committee. Fistula First Breakthrough Initiative: Targeting Catheter Last in Fistula First. Seminars Dialysis 25(3):303-310, 2012

Abstract: An arteriovenous fistula (AVF) is the optimal vascular access for hemodialysis (HD), because it is associated with prolonged survival, fewer infections, lower hospitalization rates, and reduced costs. The AVF First breakthrough initiative (FFBI) has made dramatic progress, effectively promoting the increase in the national AVF prevalence since the program's inception from 32% in May 2003 to nearly 60% in 2011. Central venous catheter (CVC) use has stabilized and recently decreased slightly for prevalent patients (treated more than 90 days), while CVC

usage in the first 90 days remains unacceptably high at nearly 80%. This high prevalence of CVC utilization suggests important specific improvement goals for FFBI. In addition to the current 66% AVF goal, the initiative should include specific CVC usage target(s), based on the KDOQI goal of less than 10% in patients undergoing HD for more than 90 days, and a substantially improved initial target from the current CVC proportion. These specific CVC targets would be disseminated through the ESRD networks to individual dialysis facilities, further emphasizing CVC avoidance in the transition from advanced CKD to chronic kidney failure, while continuing to decrease CVC by prompt conversion of CVC-based hemodialysis patients to permanent vascular access, utilizing an AVF whenever feasible.

[4] Ng LJ, Chen F, Pisoni RL, Krishnan M, Mapes D, Keen M, Bradbury BD. Hospitalization risks related to vascular access type among incident US hemodialysis patients. Nephrol Dial Transplant. 26(11):3659-66, 2011

BACKGROUND: The excess morbidity and mortality related to catheter utilization at and immediately following dialysis initiation may simply be a proxy for poor prognosis. We examined hospitalization burden related to vascular access (VA) type among incident patients who received some predialysis care.

METHODS: We identified a random sample of incident US Dialysis Outcomes and Practice Patterns Study hemodialysis patients (1996-2004) who reported predialysis nephrologist care. VA utilization was assessed at baseline and throughout the first 6 months on dialysis. Poisson regression was used to estimate the risk of all-cause and cause-specific hospitalizations during the first 6 months.

RESULTS: Among 2635 incident patients, 60% were dialyzing with a catheter, 22% with a graft and 18% with a fistula at baseline. Compared to fistulae, baseline catheter use was associated with an increased risk of all-cause hospitalization [adjusted relative risk (RR) = 1.30, 95% confidence interval (CI): 1.09-1.54] and graft use was not (RR = 1.07, 95% CI: 0.89-1.28). Allowing for VA changes over time, the risk of catheter versus fistula use was more pronounced (RR = 1.72, 95% CI: 1.42-2.08) and increased slightly for graft use (RR = 1.15, 95% CI: 0.94-1.41). Baseline catheter use was most strongly related to infection-related (RR = 1.47, 95% CI: 0.92-2.36) and VA-related hospitalizations (RR = 1.49, 95% CI: 1.06-2.11). These effects were further strengthened when VA use was allowed to vary over time (RR = 2.31, 95% CI: 1.48-3.61 and RR = 3.10, 95% CI: 1.95-4.91, respectively). A similar pattern was noted for VA-related hospitalizations with graft use. Discussion. Among potentially healthier incident patients, hospitalization risk, particularly infection and VA-related, was highest for patients dialyzing with a catheter at initiation and throughout follow-up, providing further support to clinical practice recommendations to minimize catheter placement.

[5] Block GA, Kilpatrick RD, Lowe KA, Wang W, Danese MD. CKD-Mineral and Bone Disorder and Risk of Death and Cardiovascular Hospitalization in Patients on Hemodialysis. CJASN 8:2132-2140, 2013.

BACKGROUND AND OBJECTIVES: Parathyroid hormone, calcium, and phosphate have been independently associated with cardiovascular event risk. Because these parameters may be on the same causal pathway and have been proposed as quality measures, an integrated approach to estimating event risks is needed.

DESIGN, SETTING, PARTICIPANTS, & MEASUREMENTS: Prevalent dialysis patients were followed from August 31, 2005 to December 31, 2006. A two-stage modeling approach was used. First, the 16-month probabilities of death and composite end point of death or cardiovascular hospitalization were estimated and adjusted for potential confounders. Second, patients were categorized into 1 of 36 possible phenotypes using average parathyroid hormone, calcium, and phosphate values over a 4-month baseline period. Associations among phenotypes and outcomes were estimated and adjusted for the underlying event risk estimated from the first model stage.

RESULTS: Of 26,221 patients, 98.5% of patients were in 22 groups with at least 100 patients and 20% of patients were in the reference group defined using guideline-based reference ranges for parathyroid hormone, calcium, and phosphate. Within the 22 most common phenotypes, 20% of patients were in groups with significantly ($P<0.05$) higher risk of death and 54% of patients were in groups with significantly higher risk of the composite end point relative to the in-target reference group. Increased risks ranged from 15% to 47% for death and from 8% to 55% for the composite. More than 40% of all patients were in the three largest groups with elevated composite end point risk (high parathyroid hormone, target calcium, and high phosphate; target high parathyroid hormone, target calcium, and high phosphate; and target high parathyroid hormone, target calcium, and target phosphate).

CONCLUSION: After adjusting for baseline risk, phenotypes defined by categories of parathyroid hormone, calcium, and phosphate identify patients at higher risk of death and cardiovascular hospitalization. Identifying common high-risk phenotypes may inform clinical interventions and policies related to quality of care.

[6] Pun PH, Horton JR, Middleton JP. Dialysate calcium concentration and the risk of sudden cardiac arrest in hemodialysis patients. CJASN 8:797-803, 2013.

BACKGROUND AND OBJECTIVES: The optimal dialysate calcium concentration to maintain normal mineralization and reduce risk of cardiovascular events in hemodialysis patients is debated. Guidelines suggest that dialysate Ca concentration should be lowered to avoid vascular calcification, but cardiac arrhythmias may be more likely to occur at lower dialysate Ca. Concurrent use of QT-prolonging medications may also exacerbate arrhythmic risk. This study examined the influence of serum Ca, dialysate Ca, and QT interval-prolonging medications on the risk of sudden cardiac arrest in a cohort of hemodialysis patients.

DESIGN, SETTING, PARTICIPANTS, & MEASUREMENTS: This case-control study among 43,200 hemodialysis patients occurred between 2002 and 2005; 510 patients who experienced a witnessed sudden cardiac arrest were compared with 1560 matched controls. This study examined covariate-adjusted sudden cardiac arrest risk associations with serum Ca, dialysate Ca, serum dialysate Ca gradient, and prescription of QT-prolonging medications using logistic regression techniques.

RESULTS: Patients assigned to low Ca dialysate<2.5 mEq/L were more likely to be exposed to larger serum dialysate Ca gradient and had a greater fall in BP during dialysis treatment. After accounting for covariates and baseline differences, low Ca dialysate<2.5 mEq/L (odds ratio=2.00, 95% confidence interval=1.40-2.90), higher corrected serum Ca (odds ratio=1.10, 95% confidence interval=1.00-1.30), and increasing serum dialysate Ca gradient (odds ratio=1.40,

95% confidence interval=1.10-1.80) were associated with increased risk of sudden cardiac arrest, whereas there were no significant risk associations with QT-prolonging medications.

CONCLUSIONS: Increased risk of sudden cardiac arrest associated with low Ca dialysate and large serum dialysate Ca gradients should be considered in determining the optimal dialysate Ca prescription.

[7] Ishani A, Liu J, Wetmore JB, Lowe KA, Do T, Bradbury BD, Block GA, Collins AJ. Clinical outcomes after parathyroidectomy in a nationwide cohort of patients on hemodialysis. Clin J Am Soc Nephrol. 10(1):90-7, 2015.

BACKGROUND AND OBJECTIVES: Patients receiving dialysis undergo parathyroidectomy to improve laboratory parameters in resistant hyperparathyroidism with the assumption that clinical outcomes will also improve. However, no randomized clinical trial data demonstrate the benefits of parathyroidectomy. This study aimed to evaluate clinical outcomes up to 1 year after parathyroidectomy in a nationwide sample of patients receiving hemodialysis.
DESIGN, SETTING, PARTICIPANTS, & MEASUREMENTS: Using data from the US Renal Data System, this study identified prevalent hemodialysis patients aged ≥18 years with Medicare as primary payers who underwent parathyroidectomy from 2007 to 2009. Baseline characteristics and comorbid conditions were assessed in the year preceding parathyroidectomy; clinical events were identified in the year preceding and the year after parathyroidectomy. After parathyroidectomy, patients were censored at death, loss of Medicare coverage, kidney transplant, change in dialysis modality, or 365 days. This study estimated cause-specific event rates for both periods and rate ratios comparing event rates in the postparathyroidectomy versus preparathyroidectomy periods.

RESULTS: Of 4435 patients who underwent parathyroidectomy, 2.0% died during the parathyroidectomy hospitalization and the 30 days after discharge. During the 30 days after discharge, 23.8% of patients were rehospitalized; 29.3% of these patients required intensive care. In the year after parathyroidectomy, hospitalizations were higher by 39%, hospital days by 58%, intensive care unit admissions by 69%, and emergency room/observation visits requiring hypocalcemia treatment by 20-fold compared with the preceding year. Cause-specific hospitalizations were higher for acute myocardial infarction (rate ratio, 1.98; 95% confidence interval, 1.60 to 2.46) and dysrhythmia (rate ratio 1.4; 95% confidence interval1.16 to 1.78); fracture rates did not differ (rate ratio 0.82; 95% confidence interval 0.6 to 1.1).

CONCLUSIONS: Parathyroidectomy is associated with significant morbidity in the 30 days after hospital discharge and in the year after the procedure. Awareness of clinical events will assist in developing evidence-based risk/benefit determinations for the indication for parathyroidectomy.

[8] Tentori F, McCullough K, Kilpatrick RD, Bradbury BD, Robinson BM, Kerr PG, Pisoni RL. High rates of death and hospitalization follow bone fracture among hemodialysis patients. Kidney Int. 85(1):166-73, 2014.

Abstract: Altered bone structure and function contribute to the high rates of fractures in dialysis patients compared to the general population. Fracture events may increase the risk of subsequent adverse clinical outcomes. Here we assessed the incidence of post-fracture

morbidity and mortality in an international cohort of 34,579 in-center hemodialysis patients in the Dialysis Outcomes and Practice Patterns Study (DOPPS). We estimated country-specific rates of fractures requiring a hospital admission and associated length of stay in the hospital. Incidence rates of death and of a composite event of death/rehospitalization were estimated for 1 year after fracture. Overall, 3% of participants experienced a fracture. Fracture incidence varied across countries, from 12 events/1000 patient-years (PY) in Japan to 45/1000 PY in Belgium. In all countries, fracture rates were higher in the hemodialysis group compared to those reported for the general population. Median length of stay ranged from 7 to 37 days in the United States and Japan, respectively. In most countries, postfracture mortality rates exceeded 500/1000 PY and death/rehospitalization rates exceeded 1500/1000 PY. Fracture patients had higher unadjusted rates of death (3.7-fold) and death/rehospitalization (4.0-fold) compared to the overall DOPPS population. Mortality and hospitalization rates were highest in the first month after the fracture and declined thereafter. Thus, the high frequency of fractures and increased adverse outcomes following a fracture pose a significant health burden for dialysis patients. Fracture prevention strategies should be identified and applied broadly in nephrology practices.

[9] Weinhandl ED, Arneson TJ, St Peter WL. Clinical outcomes associated with receipt of integrated pharmacy services by hemodialysis patients: a quality improvement report. Am J Kidney Dis. Sep;62(3):557-67, 2013.

Reducing medication-related problems and improving medication adherence in hemodialysis patients may improve clinical outcomes. In 2005, a large US dialysis organization created an integrated pharmacy program for its patients. We aimed to compare the outcomes of hemodialysis patients enrolled in this program and matched control patients.

STUDY DESIGN: Quality improvement report.

SETTING & PARTICIPANTS: Hemodialysis patients with concurrent Medicare and Medicaid eligibility who chose to receive program services and propensity score-matched controls; the propensity score was an estimated function of demographic characteristics, comorbid conditions, medication exposure, serum concentrations, and vascular access method.

QUALITY IMPROVEMENT PLAN: Program services included medication delivery, refill management, medication list reviews, telephonic medication therapy management, and prior authorization assistance.
OUTCOMES: Relative rates of death and hospitalization.

MEASUREMENTS: Survival estimates calculated with the Kaplan-Meier method; mortality hazards compared with Cox regression; hospitalization rates compared with Poisson regression.

RESULTS: In outcome models, there were 8,864 patients receiving integrated pharmacy services and 43,013 matched controls. In intention-to-treat and as-treated analyses, mortality HRs for patients receiving integrated pharmacy services versus matched controls were 0.92 (95% CI, 0.86-0.97) and 0.79 (95% CI, 0.74-0.84), respectively. Corresponding relative rates of hospital admissions were 0.98 (95% CI, 0.95-1.01) and 0.93 (95% CI, 0.90-0.96), respectively, and of hospital days, 0.94 (95% CI, 0.90-0.98) and 0.86 (95% CI, 0.82-0.90), respectively. Cumulative incidences of disenrollment from the pharmacy program were 23.4% at 12 months and 37.0% at 24 months.

LIMITATIONS: Patients were not randomly assigned to receive integrated pharmacy services; as-treated analyses may be biased because of informative censoring by disenrollment from the pharmacy program; data regarding use of integrated pharmacy services were lacking.

CONCLUSIONS: Receipt of integrated pharmacy services was associated with lower rates of death and hospitalization in hemodialysis patients with concurrent Medicare and Medicaid eligibility. Studies are needed to measure pharmacy program use and assess detailed clinical and economic outcomes.

[10]. Weinhandl ED, Gilbertson DT, Collins AJ. Mortality, Hospitalization, and Technique Failure in Daily Home Hemodialysis and Matched Peritoneal Dialysis Patients: A¬†Matched Cohort Study. Am J Kidney Dis. 67(1):98-110, 2016.

BACKGROUND: Use of home dialysis is growing in the United States, but few direct comparisons of major clinical outcomes on daily home hemodialysis (HHD) versus peritoneal dialysis (PD) exist.

STUDY DESIGN: Matched cohort study.

SETTING & PARTICIPANTS: We matched 4,201 new HHD patients in 2007 to 2010 with 4,201 new PD patients from the US Renal Data System database.

PREDICTOR: Daily HHD versus PD.

OUTCOMES: Relative mortality, hospitalization, and technique failure.

RESULTS: Mean time from end-stage renal disease onset to home dialysis therapy initiation was 44.6 months for HHD and 44.3 months for PD patients. In intention-to-treat analysis, HHD was associated with 20% lower risk for all-cause mortality (HR, 0.80; 95% CI, 0.73-0.87), 8% lower risk for all-cause hospitalization (HR, 0.92; 95% CI, 0.89-0.95), and 37% lower risk for technique failure (HR, 0.63; 95% CI, 0.58-0.68), all relative to PD. In the subset of 1,368 patients who initiated home dialysis therapy within 6 months of end-stage renal disease onset, HHD was associated with similar risk for all-cause mortality (HR, 0.95; 95% CI, 0.80-1.13), similar risk for all-cause hospitalization (HR, 0.96; 95% CI, 0.88-1.05), and 30% lower risk for technique failure (HR, 0.70; 95% CI, 0.60-0.82). Regarding hospitalization, risk comparisons favored HHD for cardiovascular disease and dialysis access infection and PD for bloodstream infection.

LIMITATIONS: Matching unlikely to reduce confounding attributable to unmeasured factors, including residual kidney function; lack of data regarding dialysis frequency, duration, and dose in daily HHD patients and frequency and solution in PD patients; diagnosis codes used to classify admissions.

CONCLUSIONS: These data suggest that relative to PD, daily HHD is associated with decreased mortality, hospitalization, and technique failure. However, risks for mortality and hospitalization were similar with these modalities in new dialysis patients. The interaction between modality and end-stage renal disease duration at home dialysis therapy initiation should be investigated further.

[11] Rosenblum A, Wang W, Ball LK, Latham C, Maddux FW, Lacson E. Hemodialysis catheter care strategies: A cluster-randomized quality improvement initiative. Am J Kidney Dis. 63(2):259-267, 2014.

BACKGROUND: The prevalence of central venous catheters (CVCs) for hemodialysis remains high and, despite infection-control protocols, predisposes to bloodstream infections (BSIs).

STUDY DESIGN: Stratified, cluster-randomized, quality improvement initiative.

SETTING & PARTICIPANTS: All in-center patients with a CVC within 211 facility pairs matched by region, facility size, and rate of positive blood cultures (January to March 2011) at Fresenius Medical Care, North America.

QUALITY IMPROVEMENT PLAN: Incorporate the use of 2% chlorhexidine with 70% alcohol swab sticks for exit-site care and 70% alcohol pads to perform "scrub the hubs" in dialysis-related CVC care procedures compared to usual care.

OUTCOME: The primary outcome was positive blood cultures for estimating BSI rates.

MEASUREMENTS: Comparison of 3-month baseline period from April 1 to June 30 and follow-up period from August 1 to October 30, 2011.

RESULTS: Baseline BSI rates were similar (0.85 vs 0.86/1,000 CVC-days), but follow-up rates differed at 0.81/1,000 CVC-days in intervention facilities versus 1.04/1,000 CVC-days in controls ($P = 0.02$). Intravenous antibiotic starts during the follow-up period also were lower, at 2.53/1,000 CVC-days versus 3.15/1,000 CVC-days in controls ($P < 0.001$). Cluster-adjusted Poisson regression confirmed 21%-22% reductions in both ($P < 0.001$). Extended follow-up for 3 successive quarters demonstrated a sustained reduction of bacteremia rates for patients in intervention facilities, at 0.50/1,000 CVC-days (41% reduction; $P < 0.001$). Hospitalizations due to sepsis during 1-year extended follow-up were 0.19/1,000 CVC-days (0.069/CVC-year) versus 0.26/1,000 CVC-days (0.095/CVC-year) in controls (~27% difference; $P < 0.05$).

LIMITATIONS: Inability to capture results from blood cultures sent to external laboratories, underestimation of sepsis-specific hospitalizations, and potential crossover adoption of the intervention protocol in control facilities.

CONCLUSIONS: Adoption of the new catheter care procedure (consistent with Centers for Disease Control and Prevention recommendations) resulted in a 20% lower rate of BSIs and intravenous antibiotic starts, which were sustained over time and associated with a lower rate of hospitalizations due to sepsis.

[12] Patel PR, Kallen AJ. Bloodstream infection prevention in ESRD: Forging a pathway for success. Am J Kidney Dis. 63(2):180-182, 2014

Introduction: There should be little doubt regarding the importance of infections in the hemodialysis patient population. For years, the US Renal Data System has reported increasing hospitalization rates for all infectious diagnoses and for bacteremia/sepsis in patients treated with hemodialysis.[1] In 2011, the Centers for Disease Control and Prevention (CDC) reported that

although the burden of central line–associated bloodstream infections (BSIs) in hospitalized patients had declined nationally, the estimated burden of central line–associated BSIs in people treated with outpatient hemodialysis was substantial, possibly reaching 37,000 in 2008.[2] Soon after, the US Department of Health and Human Services released their National Action Plan to Prevent Healthcare-Associated Infections (HAIs) for End Stage Renal Disease (ESRD) Facilities.[3] The Action Plan, which was developed by the Federal Steering Committee for the Prevention of HAIs in ESRD Facilities with dialysis community stakeholder input, highlighted BSIs as a top priority for national prevention efforts.

[13] Gilbertson DT, Guo H, Arneson TJ, Collins AJ. The association of pneumococcal vaccination with hospitalization and mortality in hemodialysis patients. Nephrol Dial Transplant. Sept;26(9):2934-9, 2011.

BACKGROUND: Few studies have examined the effectiveness of pneumococcal vaccination (alone or with influenza vaccination) in improving hemodialysis patient outcomes. We aimed to describe vaccination rates between 2003-2005 and to study the effects on outcomes.

METHODS: For 118,533 prevalent patients who initiated hemodialysis ≥90 days before 1 November 2003, had Medicare Part A and Part B and were aged ≥18 years, and alive through 31 October 2005, Cox proportional hazards models were used to assess pneumococcal vaccination effects on subsequent hospitalization and mortality, adjusting for demographics and comorbidity.

RESULTS: The 21% of patients who received vaccinations were older; a higher proportion were white, with diabetes as cause of end-stage renal disease and more comorbidity. Pneumococcal vaccination was associated with a statistically significant decreased mortality hazard [hazard ratio (HR) 0.94, 95% confidence interval (CI) 0.90-0.98], cardiac death (HR 0.91, 95% CI 0.85-0.97) and hospitalization for bacteremia/viremia/septicemia (HR 0.95, 95% CI 0.91-1.00). The mortality hazard was 0.73 (95% CI 0.68-0.78) for patients who received pneumococcal and influenza vaccinations.
CONCLUSIONS: The small but significant association between pneumococcal vaccination and lower mortality risk was seen despite factors associated with poor outcomes in patients most likely to be vaccinated. Pneumococcal and influenza vaccines may have beneficial synergistic effects. Hemodialysis patients may benefit from revaccination more frequently than the recommended 5-year intervals.

[14] Dalrymple LS, Mu Y, Nguyen DV, Romano PS, Chertow GM, Grimes B, Kaysen GA, Johansen KL. CJASN 10:2170-2180, 2015.

BACKGROUND AND OBJECTIVES: Infection-related hospitalizations have increased dramatically over the last 10 years in patients receiving in-center hemodialysis. Patient and dialysis facility characteristics associated with the rate of infection-related hospitalization were examined, with consideration of the region of care, rural-urban residence, and socioeconomic status.

DESIGN, SETTING, PARTICIPANTS, & MEASUREMENTS: The US Renal Data System linked to the American Community Survey and Rural-Urban Commuting Area codes was used to examine factors associated with hospitalization for infection among Medicare beneficiaries starting in-center hemodialysis between 2005 and 2008. A Poisson mixed effects model was used to

examine the associations among patient and dialysis facility characteristics and the rate of infection-related hospitalization.

RESULTS: Among 135,545 Medicare beneficiaries, 38,475 (28%) had at least one infection-related hospitalization. The overall rate of infection-related hospitalization was 40.2 per 100 person-years. Age ≥85 years old, cancer, chronic obstructive pulmonary disease, inability to ambulate or transfer, drug dependence, residence in a care facility, serum albumin <3.5 g/dl at dialysis initiation, and dialysis initiation with an access other than a fistula were associated with a ≥20% increase in the rate of infection-related hospitalization. Patients residing in isolated small rural compared with urban areas had lower rates of hospitalization for infection (rate ratio, 0.91; 95% confidence interval, 0.86 to 0.97), and rates of hospitalization for infection varied across the ESRD networks. Measures of socioeconomic status (at the zip code level), total facility staffing, and the composition of staff (percentage of nurses) were not associated with the rate of hospitalization for infection.

CONCLUSIONS: Patient and facility factors associated with higher rates of infection-related hospitalization were identified. The findings from this study can be used to identify patients at higher risk for infection and inform the design of infection prevention strategies.

[15] Gilbertson DT, Wetmore JB. Infections Requiring Hospitalization in Patients on Hemodialysis CJASN 10:2101-2103, 2015.

Introduction: Although the past decade has witnessed significant improvements in survival or patients receiving hemodialysis (HD) (1), hospitalization rates, particularly for infection, have not improved commensurately. Notable lack of progress is evident regarding hospitalizations for bacteremia/septicemia and pulmonary infections, such as pneumonia and influenza (2). For bacteremia/septicemia, first–year (incident) admission rates showed a 39% relative increase between 2003 and 2010 from 12.9% to 18.0%. Similarly, admission rates for prevalent patients increased 36% from 8.6% to 11.6%. Pneumonia/influenza hospitalization rates also did not improve between 2003 and 2010; although first–year admission rates decreased slightly (from 10.2% to 9.0%), rates for prevalent patients increased from 8.3% to 9.0%.

[16] Arneson TJ, Liu J, Qiu Y, Gilbertson DT, Foley RN, Collins AJ. Hospital treatment for fluid overload in the Medicare hemodialysis population. Clin J Am Soc Nephrol.(6):1054-63, 2010.

BACKGROUND AND OBJECTIVES: Fluid overload in hemodialysis patients sometimes requires emergent dialysis, but the magnitude of this care has not been characterized. This study aimed to estimate the magnitude of fluid overload treatment episodes for the Medicare hemodialysis population in hospital settings, including emergency departments.

DESIGN, SETTING, PARTICIPANTS, & MEASUREMENTS: Point-prevalent hemodialysis patients were identified from the Centers for Medicare and Medicaid Renal Management Information System and Standard Analytical Files. Fluid overload treatment episodes were defined by claims for care in inpatient, hospital observation, or emergency department settings with primary discharge diagnoses of fluid overload, heart failure, or pulmonary edema, and dialysis performed on the day of or after admission. Exclusion criteria included stays >5 days. Cost was defined as total Medicare allowable costs for identified episodes. Associations between patient characteristics and episode occurrence and cost were analyzed.

RESULTS: For 25,291 patients (14.3%), 41,699 care episodes occurred over a mean follow-up time of 2 years: 86% inpatient, 9% emergency department, and 5% hospital observation. Heart failure was the primary diagnosis in 83% of episodes, fluid overload in 11%, and pulmonary edema in 6%. Characteristics associated with more frequent events included age <45 years, female sex, African-American race, causes of ESRD other than diabetes, dialysis duration of 1 to 3 years, fewer dialysis sessions per week at baseline, hospitalizations during baseline, and most comorbid conditions. Average cost was $6,372 per episode; total costs were approximately $266 million.

CONCLUSIONS: Among U.S. hemodialysis patients, fluid overload treatment is common and expensive. Further study is necessary to identify prevention opportunities.

[17] Erickson KF, Winkelmayer WC, Chertow GM, Bhattacharya J. Physician visits and 30-day hospital readmissions in patients receiving hemodialysis. J Am Soc Nephrol 25:2079-2087, 2014.

Abstract: A focus of health care reform has been on reducing 30-day hospital readmissions. Patients with ESRD are at high risk for hospital readmission. It is unknown whether more monitoring by outpatient providers can reduce hospital readmissions in patients receiving hemodialysis. In nationally representative cohorts of patients in the United States receiving in-center hemodialysis between 2004 and 2009, we used a quasi-experimental (instrumental variable) approach to assess the relationship between frequency of visits to patients receiving hemodialysis following hospital discharge and the probability of rehospitalization. We then used a multivariable regression model and published hospitalization data to estimate the cost savings and number of hospitalizations that could be prevented annually with additional provider visits to patients in the month following hospitalization. In the main cohort (n=26,613), one additional provider visit in the month following hospital discharge was estimated to reduce the absolute probability of 30-day hospital readmission by 3.5% (95% confidence interval, 1.6% to 5.3%). The reduction in 30-day hospital readmission ranged from 0.5% to 4.9% in an additional four cohorts tested, depending on population density around facilities, facility profit status, and patient Medicaid eligibility. At current Medicare reimbursement rates, the effort to visit patients one additional time in the month following hospital discharge could lead to 31,370 fewer hospitalizations per year, and $240 million per year saved. In conclusion, more frequent physician visits following hospital discharge are estimated to reduce rehospitalizations in patients undergoing hemodialysis. Incentives for closer outpatient monitoring following hospital discharge could lead to substantial cost savings.

[18] Kliger AS. Maintaining safety in the dialysis facility. CJASN 10:688-695, 2015.

Abstract: Errors in dialysis care can cause harm and death. While dialysis machines are rarely a major cause of morbidity, human factors at the machine interface and suboptimal communication among caregivers are common sources of error. Major causes of potentially reversible adverse outcomes include medication errors, infections, hyperkalemia, access-related errors, and patient falls. Root cause analysis of adverse events and "near misses" can illuminate care processes and show system changes to improve safety. Human factors engineering and simulation exercises have strong potential to define common clinical team purpose, and improve processes of care. Patient observations and their participation in error reduction increase the effectiveness of patient safety efforts.

[19] Nissenson AR. Improving outcomes for ESRD patients: Shifting the quality paradigm. CJASN 9:430-434, 2014.

Abstract: The availability of life-saving dialysis therapy has been one of the great successes of medicine in the past four decades. Over this time period, despite treatment of hundreds of thousands of patients, the overall quality of life for patients with ESRD has not substantially improved. A narrow focus by clinicians and regulators on basic indicators of care, like dialysis adequacy and anemia, has consumed time and resources but not resulted in significantly improved survival; also, frequent hospitalizations and dissatisfaction with the care experience continue to be seen. A new quality paradigm is needed to help guide clinicians, providers, and regulators to ensure that patients' lives are improved by the technically complex and costly therapy that they are receiving. This paradigm can be envisioned as a quality pyramid: the foundation is the basic indicators (outstanding performance on these indicators is necessary but not sufficient to drive the primary outcomes). Overall, these basics are being well managed currently, but there remains an excessive focus on them, largely because of publically reported data and regulatory requirements. With a strong foundation, it is now time to focus on the more complex intermediate clinical outcomes-fluid management, infection control, diabetes management, medication management, and end-of-life care among others. Successfully addressing these intermediate outcomes will drive improvements in the primary outcomes, better survival, fewer hospitalizations, better patient experience with the treatment, and ultimately, improved quality of life. By articulating this view of quality in the ESRD program (pushing up the quality pyramid), the discussion about quality is reframed, and also, clinicians can better target their facilities in the direction of regulatory oversight and requirements about quality. Clinicians owe it to their patients, as the ESRD program celebrates its 40th anniversary, to rekindle the aspirations of the creators of the program, whose primary goal was to improve the lives of the patients afflicted with this devastating condition.

[20] Dasgupta I, Thomas GN, Clarke J, Sitch A, Martin J, Bieber B, Hecking M, Karaboyas A, Pisoni R, Port F, Robinson B, Rayner H. Associations between Hemodialysis Facility Practices to Manage Fluid Volume and Intradialytic Hypotension and Patient Outcomes. Clin J Am Soc Nephrol. 2019 Mar 7;14(3):385-393. doi: 10.2215/CJN.08240718. Epub 2019 Feb 5. PubMed PMID: 30723164; PubMed Central PMCID: PMC6419273.

BACKGROUND AND OBJECTIVES: Fluid overload and intradialytic hypotension are associated with cardiovascular events and mortality in patients on hemodialysis. We investigated associations between hemodialysis facility practices related to fluid volume and intradialytic hypotension and patient outcomes.

DESIGN, SETTING, PARTICIPANTS, & MEASUREMENTS: Data were analyzed from 10,250 patients in 273 facilities across 12 countries, from phase 4 of the Dialysis Outcomes and Practice Patterns Study (DOPPS; 2009-2012). Cox regression models (shared frailty) were used to estimate associations between facility practices reported by medical directors in response to the DOPPS Medical Directors Survey and all-cause and cardiovascular mortality and hospitalization, and cardiovascular events, adjusting for country, age, sex, dialysis vintage, predialysis systolic BP, cardiovascular comorbidities, diabetes, body mass index, smoking, residual kidney function, dialysis adequacy, and vascular access type.

RESULTS: Of ten facility practices tested (chosen a priori), having a protocol that specifies how often to assess dry weight in most patients was associated with lower all-cause (hazard ratio [HR], 0.78; 99% confidence interval [99% CI], 0.64 to 0.94) and cardiovascular mortality (HR,

0.72; 99% CI, 0.55 to 0.95). Routine orthostatic BP measurement to assess dry weight was associated with lower all-cause hospitalization (HR, 0.86; 99% CI, 0.77 to 0.97) and cardiovascular events (HR, 0.85; 99% CI, 0.73 to 0.98). Routine use of lower dialysate temperature to limit or prevent intradialytic hypotension was associated with lower cardiovascular mortality (HR, 0.76; 99% CI, 0.58 to 0.98). Routine use of an online volume indicator to assess dry weight was associated with higher all-cause hospitalization (HR, 1.19; 99% CI, 1.02 to 1.38). Routine use of sodium modeling/profiling to limit or prevent intradialytic hypotension was associated with higher all-cause mortality (HR, 1.36; 99% CI, 1.14 to 1.63), cardiovascular mortality (HR, 1.34; 99% CI, 1.04 to 1.73), and cardiovascular events (HR, 1.21; 99% CI, 1.03 to 1.43).
CONCLUSIONS: Hemodialysis facility practices relating to the management of fluid volume and intradialytic hypotension are associated with patient outcomes.

[21] Al Salmi I, Larkina M, Wang M, Subramanian L, Morgenstern H, Jacobson SH, Hakim R, Tentori F, Saran R, Akiba T, Tomilina NA, Port FK, Robinson BM, Pisoni RL. Missed Hemodialysis Treatments: International Variation, Predictors, and Outcomes in the Dialysis Outcomes and Practice Patterns Study (DOPPS). Am J Kidney Dis. 2018 Nov;72(5):634-643. doi: 10.1053/j.ajkd.2018.04.019. Epub 2018 Aug 23. PubMed PMID: 30146421.

RATIONALE & OBJECTIVE: Missed hemodialysis (HD) treatments not due to hospitalization have been associated with poor clinical outcomes and related in part to treatment nonadherence. Using data from the Dialysis Outcomes and Practice Patterns Study (DOPPS) phase 5 (2012-2015), we report findings from an international investigation of missed treatments among patients prescribed thrice-weekly HD.
STUDY DESIGN: Prospective observational study.
SETTING & PARTICIPANTS: 8,501 patients participating in DOPPS, on HD therapy for more than 120 days, from 20 countries. Longitudinal and cross-sectional analyses were performed based on the 4,493 patients from countries in which 4-month missed treatment risk was > 5%.
PREDICTORS: The main predictor of patient outcomes was 1 or more missed treatments in the 4 months before DOPPS phase 5 enrollment; predictors of missed treatments included country, patient characteristics, and clinical factors.
OUTCOMES: Mortality, hospitalization, laboratory measures, patient-reported outcomes, and 4-month missed treatment risk.
ANALYTICAL APPROACH: Outcomes were assessed using Cox proportional hazards, logistic, and linear regression, adjusting for case-mix and country.
RESULTS: The 4-month missed treatment risk varied more than 50-fold across all 20 DOPPS countries, ranging from < 1% in Italy and Japan to 24% in the United States. Missed treatments were more likely with younger age, less time on dialysis therapy, shorter HD treatment time, lower Kt/V, longer travel time to HD centers, and more symptoms of depression. Missed treatments were positively associated with all-cause mortality (HR, 1.68; 95% CI, 1.37-2.05), cardiovascular mortality, sudden death/cardiac arrest, hospitalization, serum phosphorus level > 5.5mg/dL, parathyroid hormone level > 300pg/mL, hemoglobin level < 10g/dL, higher kidney disease burden, and worse general and mental health.
LIMITATIONS: Possible residual confounding; temporal ambiguity in the cross-sectional analyses.
CONCLUSIONS: In the countries with a 4-month missed treatment risk > 5%, HD patients were more likely to die, be hospitalized, and have poorer patient-reported outcomes and laboratory measures when 1 or more missed treatments occurred in a 4-month period. The large variation in missed treatments across 20 nations suggests that their occurrence is potentially modifiable, especially in the United States and other countries in which missed treatment risk is high.

[22] Plantinga LC, Masud T, Lea JP, Burkart JM, O'Donnell CM, Jaar BG. Post-hospitalization dialysis facility processes of care and hospital readmissions among hemodialysis patients: a retrospective cohort study. BMC Nephrol. 2018 Jul 31;19(1):186. doi: 10.1186/s12882-018-0983-5. PubMed PMID: 30064380; PubMed Central PMCID: PMC6069998.

BACKGROUND: Both dialysis facilities and hospitals are accountable for 30-day hospital readmissions among U.S. hemodialysis patients. We examined the association of post-hospitalization processes of care at hemodialysis facilities with pulmonary edema-related and other readmissions.

METHODS: In a retrospective cohort comprised of electronic medical record (EMR) data linked with national registry data, we identified unique patient index admissions (n = 1056; 2/1/10-7/31/15) that were followed by ⩾3 in-center hemodialysis sessions within 10 days, among patients treated at 19 Southeastern dialysis facilities. Indicators of processes of care were defined as present vs. absent in the dialysis facility EMR. Readmissions were defined as admissions within 30 days of the index discharge; pulmonary edema-related vs. other readmissions defined by discharge codes for pulmonary edema, fluid overload, and/or congestive heart failure. Multinomial logistic regression to estimate odds ratios (ORs) for pulmonary edema-related and other vs. no readmissions.

RESULTS: Overall, 17.7% of patients were readmitted, and 8.0% had pulmonary edema-related readmissions (44.9% of all readmissions). Documentation of the index admission (OR = 2.03, 95% CI 1.07-3.85), congestive heart failure (OR = 1.87, 95% CI 1.07-3.27), and home medications stopped (OR = 1.81, 95% CI 1.08-3.05) or changed (OR = 1.69, 95% CI 1.06-2.70) in the EMR post-hospitalization were all associated with higher risk of pulmonary edema-related vs. no readmission; lower post-dialysis weight (by ⩾0.5 kg) after vs. before hospitalization was associated with 40% lower risk (OR = 0.60, 95% CI 0.37-0.96).

CONCLUSIONS: Our results suggest that some interventions performed at the dialysis facility in the post-hospitalization period may be associated with reduced readmission risk, while others may provide a potential existing means of identifying patients at higher risk for readmissions, to whom such interventions could be efficiently targeted.

[23] Assimon MM, Wang L, Flythe JE. Failed Target Weight Achievement Associates with Short-Term Hospital Encounters among Individuals Receiving Maintenance Hemodialysis. J Am Soc Nephrol. 2018 Aug;29(8):2178-2188. doi: 10.1681/ASN.2018010004. Epub 2018 May 23. PubMed PMID: 29793962; PubMed Central PMCID: PMC6065090.

Background Hospitalizations and 30-day readmissions are common in the hemodialysis population. Actionable clinical markers for near-term hospital encounters are needed to identify individuals who require swift intervention to avoid hospitalization. Aspects of volume management, such as failed target weight (i.e, estimated dry weight) achievement, are plausible modifiable indicators of impending adverse events. The short-term consequences of failed target weight achievement are not well established.

Methods Statistically deidentified data were
taken from a cohort of Medicare-enrolled, prevalent hemodialysis patients treated at a large dialysis organization from 2010 to 2012. We used a retrospective cohort design with repeated intervals, each consisting of 180-day baseline, 30-day exposure assessment, and 30-day follow-up period, to estimate the associations between failed target weight achievement and the risk of 30-day emergency department visits and hospitalizations. We estimated adjusted risk differences using inverse probability of exposure weighted Kaplan-Meier methods.

Results A total of 113,561 patients on hemodialysis contributed 788,722 study intervals to analyses. Patients who had a postdialysis weight >1.0 kg above the prescribed target weight in ⩾30% (versus <30%) of exposure period treatments had a higher absolute risk (risk difference) of 30-day: emergency department visits (2.13%; 95% confidence interval, 2.00% to 2.32%); and all-cause (1.47%; 95% confidence interval, 1.34% to 1.62%), cardiovascular (0.31%; 95% confidence
interval, 0.24% to 0.40%), and volume-related (0.15%; 95% confidence interval, 0.11% to 0.21%) hospitalizations.
Conclusions In the absence of objective measures of volume status, recurrent failure to achieve target weight is an easily identifiable clinical risk marker for impending hospital encounters among patients on hemodialysis.

[24] Lunney M, Lee R, Tang K, Wiebe N, Bello AK, Thomas C, Rabi D, Tonelli M, James MT. Impact of Telehealth Interventions on Processes and Quality of Care for Patients With ESRD. Am J Kidney Dis. 2018 Oct;72(4):592-600. doi:10.1053/j.ajkd.2018.02.353. Epub 2018 Apr 23. PubMed PMID: 29699884.

Caring for patients with end-stage renal disease (ESRD) requiring dialysis is intensive and expensive. Telehealth may improve the access and efficiency of ESRD care. For this perspective, we systematically reviewed studies that examined the effectiveness of telehealth versus or in addition to usual care for ESRD management. 10 studies were identified, including 7 randomized trials and 3 cohort studies. Study populations, modes of delivery (including telephone, telemetry, or videoconferencing), and the outcomes evaluated varied substantially between studies. Two studies examined telehealth interventions versus standard ESRD care and demonstrated mixed results on processes of care, no differences in laboratory surrogate markers of ESRD care, and reduced or similar rates of hospitalization. Eight studies evaluated the addition of telehealth to usual care and demonstrated no significant improvements in processes of care or surrogate laboratory measures, variable impacts on hospitalization rates, and mixed impacts on some domains of quality of life, including improvement in mental health. Although potential benefits of telehealth in ESRD care have been reported, optimal designs for delivery and elements of care that may be improved through telehealth remain uncertain.

[25] Rivara MB, Ravel V, Streja E, Obi Y, Soohoo M, Cheung AK, Himmelfarb J, Kalantar-Zadeh K, Mehrotra R. Weekly Standard Kt/V(urea) and Clinical Outcomes in Home and In-Center Hemodialysis. Clin J Am Soc Nephrol. 2018 Mar 7;13(3):445-455. doi: 10.2215/CJN.05680517. Epub 2018 Jan 11. PubMed PMID: 29326306; PubMed Central PMCID: PMC5967669.

BACKGROUND AND OBJECTIVES: Patients undergoing hemodialysis with a frequency other than thrice weekly are not included in current clinical performance metrics for dialysis adequacy. The weekly standard Kt/Vurea incorporates treatment frequency, but there are limited data on its association with clinical outcomes.
DESIGN, SETTING, PARTICIPANTS, & MEASUREMENTS: We used multivariable regression to examine the association of dialysis standard Kt/Vurea with BP and metabolic control (serum potassium, calcium, bicarbonate, and phosphorus) in patients incidental to dialysis treated with home (n=2373) or in-center hemodialysis (n=109,273). We further used Cox survival models to examine the association of dialysis standard Kt/Vurea with mortality, hospitalization, and among patients on home hemodialysis, transfer to in-center hemodialysis.
RESULTS: After adjustment for potential confounders, patients with dialysis standard Kt/Vurea <2.1 had higher BPs compared with patients with standard Kt/Vurea 2.1 to <2.3 (3.4 mm Hg higher [P<0.001] for home hemodialysis and 0.9 mm Hg higher [P<0.001] for in-center hemodialysis). There were no clinically meaningful associations between dialysis standard

Kt/Vurea and markers of metabolic control, irrespective of dialysis modality. There was no association between dialysis standard Kt/Vurea and risk for mortality, hospitalization, or transfer to in-center hemodialysis among patients undergoing home hemodialysis. Among patients on in-center hemodialysis, dialysis standard Kt/Vurea <2.1 was associated with higher risk (adjusted hazard ratio, 1.11; 95% confidence interval, 1.07 to 1.14) and standard Kt/Vurea ⩾2.3 was associated with lower risk (adjusted hazard ratio, 0.97; 95% confidence interval, 0.94 to 0.99) for death compared with standard Kt/Vurea 2.1 to <2.3. Additional analyses limited to patients with available data on residual kidney function showed similar relationships of dialysis and total (dialysis plus kidney) standard Kt/Vurea with outcomes.
CONCLUSIONS: Current targets for standard Kt/Vurea have limited utility in identifying individuals at increased risk for adverse clinical outcomes for those undergoing home hemodialysis but may enhance risk stratification for in-center hemodialysis.

[26] Brunelli SM, Du Mond C, Oestreicher N, Rakov V, Spiegel DM. Serum Potassium and Short-term Clinical Outcomes Among Hemodialysis Patients: Impact of the Long Interdialytic Interval. Am J Kidney Dis. 2017 Jul;70(1):21-29. doi: 10.1053/j.ajkd.2016.10.024. Epub 2017 Jan 19. PubMed PMID: 28111027.

BACKGROUND: Hyperkalemia is common among hemodialysis patients and is associated with morbidity and mortality. The long interdialytic interval is likewise associated with adverse outcomes. However, the interplay among serum potassium, dialysis cycle phase, and clinical outcomes has not been examined.
STUDY DESIGN: Retrospective observational study.
SETTING & PARTICIPANTS: 52,734 patients receiving in-center hemodialysis at a large dialysis organization during 2010 and 2011 contributed 533,889 potassium measurements (230,634 on Monday; 285,522 on Wednesday; 17,733 on Friday). PREDICTOR: Serum potassium concentration, day of the week of potassium measurement.
OUTCOMES: Death, hospitalization, emergency department (ED) visit.
RESULTS: There was a significant association between higher serum potassium and risk of hospitalization within 96 hours that was of greater magnitude on Fridays (389 hospitalizations) than Mondays or Wednesdays (4,582 and 4,629 hospitalizations, respectively; P for interaction = 0.008). Serum potassium of 5.5 to <6.0 (vs the referent category of 4.0-<4.5 mEq/L) was associated with increased risk of hospitalization on Fridays, with an adjusted OR of 1.68 (95% CI, 1.22-2.30). However, serum potassium of 5.5 to <6.0 mEq/L was associated with only mild elevation of risk on Mondays and no significantly increased risk on Wednesdays (adjusted ORs of 1.12 [95% CI, 1.00-1.24] and 1.04 [95% CI, 0.94-1.16], respectively). Associations of elevated serum potassium (6.0-<6.5 mEq/L or greater) with death and ED visit were significant, but did not differ based on day of the week.
LIMITATIONS: There were insufficient observations to detect effect modification by day of the week for deaths, ED visits, and specific causes of hospitalizations. Confounding may have influenced results.
CONCLUSIONS: Higher serum potassium is associated with increased short-term risk of hospitalization, ED visit, and death. The association between serum potassium and hospitalization risk is modified by day of the week, consistent with a contribution of accumulated potassium to adverse outcomes following the long interdialytic interval. Further work is needed to determine whether directed interventions ameliorate this risk.

[27] Wong MM, McCullough KP, Bieber BA, Bommer J, Hecking M, Levin NW, McClellan WM, Pisoni RL, Saran R, Tentori F, Tomo T, Port FK, Robinson BM. Interdialytic Weight Gain: Trends, Predictors, and

Associated Outcomes in the International Dialysis Outcomes and Practice Patterns Study (DOPPS). Am J Kidney Dis. 2017 Mar;69(3):367-379. doi: 10.1053/j.ajkd.2016.08.030. Epub 2016 Nov 17. PubMed PMID: 27866963.

BACKGROUND: High interdialytic weight gain (IDWG) is associated with adverse outcomes in hemodialysis (HD) patients. We identified temporal and regional trends in IDWG, predictors of IDWG, and associations of IDWG with clinical outcomes.

STUDY DESIGN: Analysis 1: sequential cross-sections to identify facility- and patient-level predictors of IDWG and their temporal trends. Analysis 2: prospective cohort study to assess associations between IDWG and mortality and hospitalization risk.

SETTING & PARTICIPANTS: 21,919 participants on HD therapy for 1 year or longer in the Dialysis Outcomes and Practice Patterns Study (DOPPS) phases 2 to 5 (2002-2014).

PREDICTORS: Analysis 1: study phase, patient demographics and comorbid conditions, HD facility practices. Analysis 2: relative IDWG, expressed as percentage of post-HD weight (<0%, 0%-0.99%, 1%-2.49%, 2.5%-3.99% [reference], 4%-5.69%, and ⩾5.7%).

OUTCOMES: Analysis 1: relative IDWG as a continuous variable using linear mixed models; analysis 2: mortality; all-cause and cause-specific hospitalization using Cox regression, adjusting for potential confounders.

RESULTS: From phase 2 to 5, IDWG declined in the United States (-0.29kg; -0.5% of post-HD weight), Canada (-0.25kg; -0.8%), and Europe (-0.22kg; -0.5%), with more modest declines in Japan and Australia/New Zealand. Among modifiable factors associated with IDWG, the most notable was facility mean dialysate sodium concentration: every 1-mEq/L greater dialysate sodium concentration was associated with 0.13 (95% CI, 0.11-0.16) greater relative IDWG. Compared to relative IDWG of 2.5% to 3.99%, there was elevated risk for mortality with relative IDWG⩾5.7% (adjusted HR, 1.23; 95% CI, 1.08-1.40) and elevated risk for fluid-overload hospitalization with relative IDWG⩾4% (HRs of 1.28 [95% CI, 1.09-1.49] and 1.64 [95% CI, 1.27-2.13] for relative IDWGs of 4%-5.69% and ⩾5.7%, respectively).

LIMITATIONS: Possible residual confounding. No dietary salt intake data.

CONCLUSIONS: Reductions in IDWG during the past decade were partially explained by reductions in dialysate sodium concentration. Focusing quality improvement strategies on reducing occurrences of high IDWG may improve outcomes in HD patients.

[28] Erickson KF, Winkelmayer WC, Chertow GM, Bhattacharya J. Hemodialysis Hospitalizations and Readmissions: The Effects of Payment Reform. Am J Kidney Dis. 2017 Feb;69(2):237-246. doi: 10.1053/j.ajkd.2016.08.033. Epub 2016 Nov 14. PubMed PMID: 27856087; PubMed Central PMCID: PMC5263112.

BACKGROUND: In 2004, the Centers for Medicare & Medicaid Services changed reimbursement for physicians and advanced practitioners caring for patients receiving hemodialysis from a capitated to a tiered fee-for-service system, encouraging increased face-to-face visits. This early version of a pay-for-performance initiative targeted a care process: more frequent provider visits in hemodialysis. Although more frequent provider visits in hemodialysis are associated with fewer hospitalizations and rehospitalizations, it is unknown whether encouraging more frequent visits through reimbursement policy also yielded these benefits.

STUDY DESIGN: We used a retrospective cohort interrupted time-series study design to examine whether the 2004 nephrologist reimbursement reform led to reduced hospitalizations and rehospitalizations. We also used published data to estimate a range of annual economic costs associated with more frequent visits. SETTING & PARTICIPANTS: Medicare beneficiaries in the United States receiving hemodialysis in the 2 years prior to and following reimbursement reform.

PREDICTOR: The 2 years following nephrologist reimbursement reform.
OUTCOMES: Odds of hospitalization and 30-day hospital readmission for all causes and fluid overload; US dollars.
RESULTS: We found no significant change in all-cause hospitalization or rehospitalization and slight reductions in fluid overload hospitalization and rehospitalization following reimbursement reform; the estimated economic cost associated with additional visits ranged from $13 to $87 million per year, depending on who (physicians or advanced practitioners) spent additional time visiting patients and how much additional effort was involved.
LIMITATIONS: Due to limited information about how much additional time providers spent seeing patients after reimbursement reform, we could only examine a range of potential economic costs associated with the reform.
CONCLUSIONS: A Medicare reimbursement policy designed to encourage more frequent visits during outpatient hemodialysis may have been costly. The policy was associated with fewer hospitalizations and rehospitalizations for fluid overload, but had no effect on all-cause hospitalizations or rehospitalizations.

[29] Maduell F, Ramos R, Varas J, Martin-Malo A, Molina M, Pérez-Garcia R, Marcelli D, Moreso F, Aljama P, Merello JI. Hemodialysis patients receiving a greater Kt dose than recommended have reduced mortality and hospitalization risk. Kidney Int. 2016 Dec;90(6):1332-1341. doi: 0.1016/j.kint.2016.08.022. Epub 2016 Oct 22. PubMed PMID: 27780586.

Achieving an adequate dialysis dose is one of the key goals for dialysis treatments. Here we assessed whether patients receiving the current cleared plasma volume (Kt), individualized for body surface area per recommendations, had improved survival and reduced hospitalizations at 2 years of follow-up. Additionally, we assessed whether patients receiving a greater dose gained more benefit. This prospective, observational, multicenter study included 6129 patients in 65 Fresenius Medical Care Spanish facilities. Patients were classified monthly into 1 of 10 risk groups based on the difference between achieved and target Kt. Patient groups with a more negative relationship were significantly older with a higher percentage of diabetes mellitus and catheter access. Treatment dialysis time, effective blood flow, and percentage of on-line hemodiafiltration were significantly higher in groups with a higher dose. The mortality risk profile showed a progressive increase when achieved minus target Kt became more negative but was significantly lower in the group with 1 to 3 L clearance above target Kt and in groups with greater increases above target Kt. Additionally, hospitalization risk appeared significantly reduced in groups receiving 9 L or more above the minimum target. Thus, prescribing an additional 3 L or more above the minimum Kt dose could potentially reduce mortality risk, and 9 L or more reduce hospitalization risk. As such, future prospective studies are required to confirm these dose effect findings.

[30] Choi HH, Han KT, Nam CM, Moon KT, Kim W, Park EC. Association between human resources and risk of hospitalisation in end-stage renal disease outpatients receiving haemodialysis: a longitudinal cohort study using claim data during 2013-2014. BMJ Open. 2016 Aug 17;6(8):e011319. doi: 10.1136/bmjopen-2016-011319. Erratum in: BMJ Open. 2016 Sep 13;6(9):e011319corr1. PubMed PMID: 27534988;
PubMed Central PMCID: PMC5013410.

OBJECTIVE: The number of patients requiring haemodialysis has gradually increased in South Korea. Owing to this growth, concerns have been raised regarding haemodialysis quality of care, and healthcare professionals must consider alternatives for appropriate management of patients with chronic kidney disease (CKD). Therefore, we investigated the association between

risk of hospitalization of outpatients who received haemodialysis due to end-stage renal disease (ESRD) and the human resources of the haemodialysis unit.
SETTING: We used data from National Health Insurance (NHI) claims during October 2013 to September 2014.
PARTICIPANTS: These data comprised 40 543 outpatients with ESRD (4 751 047 outpatient cases) who received haemodialysis.
INTERVENTIONS: No interventions were made.
OUTCOME MEASURE: We performed Poisson regression analysis using a generalized estimating equation that included both patient and haemodialysis unit characteristics to examine the factors associated with hospitalisation of outpatients with ESRD.
RESULTS: Among 4 751 047 outpatient cases, 27 997 (0.59%) were hospitalized during the study period. A higher proportion of haemodialysis patient care specialists and a higher number of nurses experienced in haemodialysis were inversely associated with the risk of hospitalisation (per 10% increase in haemodialysis patient care specialists: relative risk (RR)=0.987, 95% CI 0.981 to 0.993; per 10-person increase in nurses who provided haemodialysis: RR=0.876, 95% CI 0.833 to 0.921). In addition, such associations were greater in severe patients.
CONCLUSIONS: Our findings suggest that haemodialysis units with high-quality, haemodialysis-specialised human resources could positively affect the outcomes of outpatients with ESRD. Based on our findings, health policymakers and professionals should implement strategies for the optimal management of patients with CKD.

[31] Dalrymple LS, Mu Y, Nguyen DV, Romano PS, Chertow GM, Grimes B, Kaysen GA, Johansen KL. Risk Factors for Infection-Related Hospitalization in In-Center Hemodialysis. Clin J Am Soc Nephrol. 2015 Dec 7;10(12):2170-80. doi: 10.2215/CJN.03050315. Epub 2015 Nov 13. PubMed PMID: 26567370; PubMed Central PMCID: PMC4670763.

BACKGROUND AND OBJECTIVES: Infection-related hospitalizations have increased dramatically over the last 10 years in patients receiving in-center hemodialysis. Patient and dialysis facility characteristics associated with the rate of infection-related hospitalization were examined, with consideration of the region of care, rural-urban residence, and socioeconomic status.
DESIGN, SETTING, PARTICIPANTS, & MEASUREMENTS: The US Renal Data System linked to the American Community Survey and Rural-Urban Commuting Area codes was used to examine factors associated with hospitalization for infection among Medicare beneficiaries starting in-center hemodialysis between 2005 and 2008. A Poisson mixed effects model was used to examine the associations among patient and dialysis facility characteristics and the rate of infection-related hospitalization.
RESULTS: Among 135,545 Medicare beneficiaries, 38,475 (28%) had at least one infection-related hospitalization. The overall rate of infection-related hospitalization was 40.2 per 100 person-years. Age $\geqslant$ 85 years old, cancer, chronic obstructive pulmonary disease, inability to ambulate or transfer, drug dependence, residence in a care facility, serum albumin <3.5 g/dl at dialysis initiation, and dialysis initiation with an access other than a fistula were associated with a $\geqslant$ 20% increase in the rate of infection-related hospitalization. Patients residing in isolated small rural compared with urban areas had lower rates of hospitalization for infection (rate ratio, 0.91; 95% confidence interval, 0.86 to 0.97), and rates of hospitalization for infection varied across the ESRD networks. Measures of socioeconomic status (at the zip code level), total facility staffing, and the composition of staff (percentage of nurses) were not associated with the rate of hospitalization for infection.

CONCLUSIONS: Patient and facility factors associated with higher rates of infection-related hospitalization were identified. The findings from this study can be used to identify patients at higher risk for infection and inform the design of infection prevention strategies.

[32] Wang IK, Lin CL, Lin PC, Chang SN, Chou CY, Yen TH, Chang CT, Huang CC, Sung FC. Seasonal influenza vaccination is associated with reduced morbidity and mortality in peritoneal dialysis patients. Nephrol Dial Transplant. 2016 Feb;31(2):269-74. doi: 10.1093/ndt/gfv360. Epub 2015 Oct 8. PubMed PMID: 26453199.

BACKGROUND: Studies on the effectiveness of seasonal influenza vaccination in peritoneal dialysis (PD) patients are limited. The aim of the present study is to evaluate the effectiveness of seasonal influenza vaccination in reducing morbidity and mortality in incident end-stage renal disease patients on PD.

METHODS: From Taiwan's National Health Insurance Research Database, we identified 2089 incident PD patients with seasonal influenza vaccination and 2089 propensity score matched incident PD patients without the vaccination during 1998-2010. Each study subject was followed up to measure the 12-month incident cardiovascular and infectious diseases, and deaths. The effects of multi-year vaccinations were also estimated.

RESULTS: Compared with the non-vaccinated cohort, the vaccinated cohort had a lower hospitalization rate (68.5 versus 80.2 per 100 person-years) with an adjusted hazard ratio (aHR) of 0.85 [95% confidence interval (CI) = 0.78-0.92]. Hazards of hospitalization were significantly reduced for sepsis (aHR = 0.79, 95% CI = 0.65-0.96), heart disease (aHR = 0.74, 95% CI = 0.63-0.89) and intensive care (aHR = 0.85, 95% CI = 0.73-0.99). In addition, hazards of peritonitis (aHR = 0.84, 95% CI = 0.73-0.97) and overall mortality (aHR = 0.66, 95% CI = 0.55-0.78) were also reduced. The aHR of mortality was reduced much further to 0.28 (95% CI = 0.22-0.35) for those with multiple-year vaccinations.

CONCLUSIONS: Seasonal influenza vaccination for PD patients is associated with significant reduction in morbidities and a 34% reduction in mortality. Multi-year vaccinations could reduce the death hazard further to 72%.

[33] Brunelli SM, Sibbel S, Do TP, Cooper K, Bradbury BD. Facility Dialysate Calcium Practices and Clinical Outcomes Among Patients Receiving Hemodialysis: A Retrospective Observational Study. Am J Kidney Dis. 2015 Oct;66(4):655-65. doi: 10.1053/j.ajkd.2015.03.038. Epub 2015 May 23. PubMed PMID: 26015274.

BACKGROUND: Some US dialysis facilities have reduced default dialysate calcium concentrations from 2.5 mEq/L to lower levels. There has been no rigorous systematic examination of the effects of such a reduction on clinical and biochemical outcomes.

STUDY DESIGN: Retrospective cohort study.

SETTING & PARTICIPANTS: Medicare-eligible patients who received in-center hemodialysis at a large dialysis organization in January 2008 to December 2010. PREDICTOR: Facility conversion from predominant use (≥75% patients) of 2.50-mEq/L dialysate calcium to predominant use of lower dialysate calcium concentrations versus maintenance of predominant use of 2.50-mEq/L dialysate calcium.

OUTCOMES: All-cause and cause-specific mortality and hospitalization, laboratory markers of metabolic bone disease, and drug utilization.

MEASUREMENTS: Hierarchical mixed linear and Poisson models were fit to compare pre- to postconversion differences in outcomes between converter and matched control facilities. Results, expressed as relative rate ratios (RRRs) and delta-delta (change in mean values), were

estimated for early (months 0-2) and late (months 3-12) postconversion to allow for possible latent effects.
RESULTS: Facility conversion was associated with greater rates of hospitalization for heart failure exacerbation (late RRR, 1.27 [95% CI, 1.06-1.51]), hypocalcemia (early RRR, 1.19 [95% CI, 1.05-1.35]; late RRR, 1.39 [95% CI, 1.20-1.60]), and intradialytic hypotension (early RRR, 1.07 [95% CI, 1.02-1.11]; late RRR, 1.05 [95% CI, 1.01-1.10]), but no differences were observed for all-cause mortality or hospitalization rates. Facility conversion was also associated with comparative temporal decreases in serum calcium level, increases in serum phosphate and parathyroid hormone levels, and increases in use of phosphate binders, vitamin D, and calcimimetics.
LIMITATIONS: Possible residual confounding, generalizability beyond Medicare patients uncertain.
CONCLUSIONS: There are potential safety concerns associated with the default use of dialysate calcium concentrations < 2.50 mEq/L, as well as biochemical evidence of poorer disease control despite associated greater medication use. Individualization of dialysate calcium concentration rather than predominant use of dialysate calcium concentrations < 2.50 mEq/L should be considered.

[34] Marrufo G, Negrusa B, Ullman D, Hirth R, Messana J, Maughan B, Nelson J, Lindsey N, Gregory D, Svoboda R, Melin C, Chung A, Dahlerus C, Nahra T, Jiao A, McKeithen K, and Gilfix Z. Comprehensive End-Stage Renal Disease Care (CEC) Model Performance Year 2 Annual Evaluation Report. Prepared for: Centers for Medicare & Medicaid Services. September 2019. [No abstract available] https://innovation.cms.gov/Files/reports/cec-annrpt-py2.pdf

1a.3. SYSTEMATIC REVIEW(SR) OF THE EVIDENCE (for INTERMEDIATE OUTCOME, PROCESS, OR STRUCTURE PERFORMANCE MEASURES, INCLUDING THOSE THAT ARE INSTRUMENT-BASED) If the evidence is not based on a systematic review go to section 1a.4) If you wish to include more than one systematic review, add additional tables.

What is the source of the systematic review of the body of evidence that supports the performance measure? A systematic review is a scientific investigation that focuses on a specific question and uses explicit, prespecified scientific methods to identify, select, assess, and summarize the findings of similar but separate studies. It may include a quantitative synthesis (meta-analysis), depending on the available data. (IOM)

☐ Clinical Practice Guideline recommendation (with evidence review)

☐ US Preventive Services Task Force Recommendation

☐ Other systematic review and grading of the body of evidence (*e.g., Cochrane Collaboration, AHRQ Evidence Practice Center*)

☐ Other

_____

1a.4 OTHER SOURCE OF EVIDENCE
If source of evidence is NOT from a clinical practice guideline, USPSTF, or systematic review, please describe the evidence on which you are basing the performance measure.

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

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

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

NATIONAL QUALITY FORUM—Measure Testing (subcriteria 2a2, 2b1-2b6)

Measure Number (*if previously endorsed*)**:** 1463
Measure Title: Standardized Hospitalization Ratio for Dialysis Facilities
Date of Submission: 1/5/2020
Type of Measure:

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

1. DATA/SAMPLE USED FOR ALL TESTING OF THIS MEASURE
Often the same data are used for all aspects of measure testing. In an effort to eliminate duplication, the first five questions apply to all measure testing. If there are differences by aspect of testing,(e.g., reliability vs. validity) be sure to indicate the specific differences in question 1.7.

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

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

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

2016 Submission

Data are derived from an extensive national ESRD patient database, which is primarily based on the CMS Consolidated Renal Operations in a Web-enabled Network (CROWN) system. The CROWN data include 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 data), the historical Standard Information Management System (SIMS) database (formerly maintained by the 18 ESRD Networks until replaced by CROWNWeb in May 2012), the National Vascular Access Improvement Initiative's Fistula First Catheter Last project (in CROWNWeb since May 2012), Medicare dialysis and hospital payment records, transplant data from the Organ Procurement and Transplant Network (OPTN), the Nursing Home Minimum Dataset, the Quality Improvement Evaluation System (QIES) Workbench, which includes data from the Certification and Survey Provider Enhanced Report System (CASPER), the Dialysis Facility Compare (DFC) and the Social Security Death Master File. The database is comprehensive for Medicare patients. Non-Medicare patients are included in all sources except for the Medicare payment records. CROWNWeb provides tracking by dialysis provider and treatment modality for non-Medicare patients. Information on hospitalizations is obtained from Part A Medicare Inpatient Claims Standard Analysis Files (SAFs), and past-year comorbidity is obtained from multiple Part A types (inpatient, home health, hospice, skilled nursing facility claims) and Part B outpatient types of Medicare Claims SAFs.

2019 Submission

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.

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.

1.3. What are the dates of the data used in testing? Click here to enter date range

2016 submission: Calendar years 2010 through 2013

2019 submission: January 2015- December 2018

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

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

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

2016 Submission

For each year of the four years from 2010-2013 there were 5,406, 5,582, 5,708 and 5,863 facilities, respectively.

2019 Submission

For each year of the four years from 2015-2018 there were 7,045, 7,316, 7,590 and 7,890 facilities, respectively.

Table 1. Number of facilities and median facility size by year

Year	Total Facilities	Total Patients	Median Patients Per Facility
2015	7,045	461,346	64
2016	7,316	474,663	64
2017	7,590	486,635	64
2018	7,890	492,665	62

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

2016 Submission

Medicare dialysis patients were included in the testing and analysis for each of the four years from 2010-2013 of which there were 377,675, 387,249, 396,167 and 403,337 patients, respectively.

2019 Submission

Medicare dialysis patients were included in the testing and analysis for each of the four years from 2015-2018 of which there were 461,346, 474,663, 486,635 and 492,665 patients, respectively.

Table 2. Descriptives of Patient Characteristics Included in the Measure

Patient Demographics	Percent
Age	
Patient Age: 0-18	0.2
Patient Age: 18-24	0.5
Patient Age: 25-44	9.3
Patient Age: 45-59	24.0
Patient Age: 60-74	41.6
Patient Age: 75+	24.5
Sex (% female)	43.7
ESRD due to Diabetes (%)	48.0
Medicare coverage(%)	
Medicare primary + Medicaid	31.0
Medicare primary + no Medicaid	38.4
HMO	20.9
Medicare secondary/Other	9.5
Time since Start of ESRD	
91 days-6 months	12.1
6 months-1 year	14.2
1-2 years	17.3
2-3 years	14.9
3-5 years	17.8
5+ years	23.8
Employment status 6 months prior to ESRD (%)	
Unemployed	21.5
Employed	17.5
Other/Unknown *	61.1
Race (%)	
White	60.4
Black	32.1
Asian/Pacific Islander	5.1
Native American/Alaskan Native	1.1
Other/Unknown	1.4
Ethnicity (%)	
Hispanic	16.5
Non-Hispanic/Unknown	83.5

* Other/Unknown groups includes Homemaker, Retired due to age/preference, retired due to disability, Medical leave of absence, or missing employment status. Note: Some categories do not sum to 100% due to rounding.

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

N/A

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

2016 Submission

Patient level:

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

**Assessed at the start of time at risk based on calendar year and facility assignment. Medicare coverage in the model was defined as:*
1. Medicare as primary and Medicaid
2. Medicare as primary and NO Medicaid
3. Medicare as secondary or Medicare HMO

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

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

- Unemployment rate (%)
- Median family income (rescaled as (income-60,000)/10,000)
- Income disparity
- Families below the poverty level (%)
- Single-parent households w/ children <18 (%)
- Home ownership rate (%)
- Median home value (rescaled as (homevalue-200,000)/100,000)
- Median monthly mortgage (rescaled as (mortgage-1,500)/1,000)
- Median gross rent (rescaled as (rent-900)/1,000)
- Population (aged 25+) with <9 years of education (%)
- Population (aged 25+) without high school diploma (%)

2019 Submission

Patient level:

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

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

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2a2. RELIABILITY TESTING

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

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

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

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

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

2011 Submission

Reliability of the Standardized Hospital Ratio for Admissions was assessed using data on hospitalizations among ESRD patients over a three year period of 2006-2008 for 4338 dialysis centers. Data for the hospitalization measures are derived from an extensive national ESRD patient database, which is largely derived from the Standard Information Management System (SIMS) database maintained by the 18 ESRD Networks, the CMS Annual Facility Survey (Form CMS-2744), Medicare dialysis and hospital payment records, the CMS Medical Evidence Form (Form CMS-2728), transplant data from the Organ Procurement and Transplant Network (OPTN), the Death Notification Form (Form CMS-2746), the Nursing Home Minimum Dataset, and the Social Security Death Master File. The database is comprehensive for Medicare patients. Information on hospitalizations is obtained from Medicare Inpatient Claims Standard Analysis Files (SAFs).

To assess reliability, we assessed the degree to which the measures were consistent year to year. If one looks at two adjacent time intervals, one should expect that a reliable measure will exhibit correlation over these periods since large changes in patterns affecting the measure should not occur for most

centers over shorter periods. Year to year variability in the SHR values was assessed across the years 2006, 2007 and 2008 based on the 4338 dialysis centers for which an SHR is reported in the 2010 DFRs.

2016 Submission

The reliability of the SHR was assessed using data among Medicare ESRD dialysis patients during 2010-2013. If the measure were a simple average across individuals in the facility, the usual approach for determining measure reliability would be a one-way analysis of variance (ANOVA), in which the between and within facility variation in the measure is determined. The inter-unit reliability (IUR) measures the proportion of the total variation of a measure that is attributable to the between-facility variation. The SHR, however, is not a simple average and we instead estimate the IUR using a bootstrap approach, which uses a resampling scheme to estimate the within facility variation that cannot be directly estimated by ANOVA. A small IUR (near 0) reveals that most of the variation of the measures between facilities is driven by random noise, indicating the measure would not be a good characterization of the differences among facilities, whereas a large IUR (near 1) indicates that most of the variation between facilities is due to the real difference between facilities.

Here we describe our approach to calculating IUR. Let $T_1,\ldots,T_N$ be the SHR for these facilities. Within each facility, select at random and with replacement B bootstrap samples. Our numerical experiments reveal that B=100 is sufficient. That is, if the ith facility has n_i subjects, randomly draw with replacement n_i subjects from those in the same facility, find their corresponding SHR_i and repeat the process B (say, 100) times. Thus, for the ith facility, we have bootstrapped SHRs of $T^*_{i1}\ldots, T^*_{i100}$. Let S^*_i be the sample variance of this bootstrap sample. From this it can be seen that

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

is a bootstrap estimate of the within-facility variance in the SRR, namely $\sigma^2_{t,w}$'.Calling on formulas from the one way analysis of variance, an estimate of the overall variance of T_i is

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

where

$$\bar{T} = \sum n_i T_i / \sum n_i$$

is the weighted mean of the observed SRR and

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

is approximately the average facility size (number of patients per facility). Note that s_t^2 is an estimate of $\sigma_b^2 + \sigma_{t,w}^2$ where σ_b^2 is the between-facility variance, the true signal reflecting the differences across facilities. Thus, the IUR, which is defined by

$$IUR = \frac{\sigma_b^2}{\sigma_b^2 + \sigma_{t,w}^2}$$

can be estimated with $(s_t^2 - s_{t,w}^2)/s_t^2$

The SHR calculation only included facilities with at least 5 patient years at risk.

2019 Submission

The methodology described above [3] has been applied to the IUR calculation for this submission. However, in prior submissions, if a patient transferred facilities such that no single facility had treated the patient for > 60 days, then that time at risk was assigned to a virtual facility and that virtual facility was included in the IUR calculation. For the current submission, patients who were treated at a facility for < 60 days and therefore could not be assigned a facility were not included in the IUR calculation.

To assess more directly the value of SHR in identifying facilities with extreme outcomes, we also computed an additional metric of reliability, termed the profile IUR (PIUR) [1]. The PIUR was developed since the IUR can be quite small if there are many facilities which have outcomes similar to the national norm, even though the measure is still very useful to identify facilities with extreme outcomes [2]. The PIUR is based on the measure's ability to consistently flag the same facilities. We proceed in two steps: first, we evaluate the ability of a measure to consistently profile facilities with extreme outcomes; second, we use the IUR to calibrate PIUR. Specifically, we consider a sample-splitting approach: within each facility randomly split patients into two equal-sized subgroups. For a given threshold (e.g. p-value or z-score in a hypothesis testing procedure), determine whether each facility is identified as extreme based on the first and the second subgroups. Repeat this process 100 times to estimate the probability that, given a facility is classified as extreme based on the first subgroup, it is also classified as extreme based on the second subgroup. This empirical reflagging rate is calibrated to give the PIUR by determining the IUR value that would yield this reflagging rate in the absence of outliers. The PIUR measures reliability in terms of the probability of reflagging rates but is on the same scale as IUR. The PIUR is substantially larger than the IUR when the data include many outliers or extreme values that are not captured in the IUR itself.

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

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

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

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

2011 Submission

The correlation between SHR admissions across adjacent years (2006 versus 2007 and 2007 vs 2008) was approximately 0.67 indicating that centers with large or small SHR tended to have larger or smaller SHR on the following year. These correlations were highly significant. Similarly, there was persistence in SHRs that were significant from year to year. For example, there were 4.3% of facilities that had significant evidence of a true SHR of at least 1.2 in 2006. Of those that were significantly larger than 1.2 in 2006, 1.8/4.3 = 42% were again significantly larger than 1.2 in 2007. Of those that were not significant in 2006, only 2.5% were found to be significantly larger than 1.2 in 2007.

The measure is based on complete data and is not subject to judgment or rater variability. Hence the measures of inter-rater variability are not relevant here.

2016 Submission

Overall, we found that IURs for the one-year SHRs have a range of 0.70-0.72 across the years 2010, 2011, 2012 and 2013, which indicates that over two-thirds of the variation in the one-year SHR can be attributed to the between-facility differences and less than one-third to within-facility variation.

Table 1: IUR for one-year SHR, Overall and by Facility Size, 2010-2013

	2010		2011		2012		2013	
Facility Size (Number of patients)	IUR	N	IUR	N	IUR	N	IUR	N
All	0.72	5407	0.71	5583	0.70	5709	0.70	5864
Small (<=50)	0.54	1864	0.51	1921	0.48	1977	0.46	2028
Medium (51–87)	0.65	1702	0.63	1785	0.58	1825	0.57	1930
Large (>=88)	0.81	1841	0.81	1877	0.81	1907	0.82	1906

2019 Submission

Table 3: IUR and PIUR for SHR by Year

Year	IUR	PIUR	N
2015	0.59	0.85	6339
2016	0.57	0.84	6520
2017	0.53	0.78	6783
2018	0.53	0.75	7041

As noted above, the PIUR measures reliability in terms of reflagging rates but is placed on the same scale as IUR. The higher PIUR compared to the IUR indicates the presence of outliers or heavier tails among the providers, which is not captured in the IUR itself. If there are no outliers, one should expect the PIUR to be similar to the IUR; but in cases where there are outlier providers, even measures with a low IUR can have relatively high PIUR and can be very useful for identifying extreme providers.

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

2011 Submission

This was not a question on the 2011 Submission Form.

2016 Submission

This value of IUR indicates a high degree of reliability. When stratified by facility size, we find that, as expected, larger facilities have greater IUR.

2019 Submission

The value obtained for the IUR is moderate in size. The PIUR is larger and demonstrates that the SHR is effective at detecting outlier facilities and statistically meaningful differences in performance scores across dialysis facilities.

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2b1. VALIDITY TESTING

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

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

☒ **Performance measure score**

☒ **Empirical validity testing**

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

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

2011 Submission

Validity of the Standardized Hospital Ratio for Admissions was assessed using data on hospitalizations as well as other quality measures among ESRD patients over a three year period of 2006-2008. We examined the validity of the measure by examining its covariability with other measures of quality as well as by examining the relationship of the overall hospitalization measure with measures that were more directly focused on specific causes.

We have assessed the validity of the measure through various comparisons of this measure with other quality measures in use. Also, hospitalization measures were reviewed by a TEP in 2007 and overall measures based on admissions and on days were recommended for inclusion in the Dialysis Facility reports. In addition, hospitalization is a major cost factor in the management of ESRD patients as noted earlier, so there is here a very strong case for face validity of the SHR admissions measure.

2016 Submission

We have assessed the validity of the measure through various comparisons of this measure with other quality measures in use, using Spearman correlations.

The measure is also maintained on face validity. Hospitalization measures were reviewed by a TEP in 2007 and overall measures based on admissions and on days were recommended for inclusion in the Dialysis Facility Reports. In 2015, a TEP was held specifically to consider prevalent comorbidity

adjustments for inclusion in the measure. The TEP's recommendations are reflected in the risk adjustment methodology. In addition, hospitalization is a major cost factor in the management of ESRD patients as noted earlier, further establishing a very strong case for face validity of the SHR admissions measure.

2019 Submission

Using Spearman correlation we assessed the validity of the SHR admissions measure by testing associations with other implemented quality measures.

Negative Relationships

- Vascular Access: Standardized Fistula Rate – We expect a negative association between SFR and SHR. Successfully creating an AVF is generally seen as representing a robust process to coordinate care outside of the dialysis facility, and potentially reduces the likelihood of adverse events, like infection that can increase the risk of patient hospitalization. Higher rates of the facility level SFR will be negatively associated with hospitalization as measured by SHR.
- Kt/V ≥ 1.2: We expect a negative association between the percentage of patients with Kt/V>= 1.2 and SHR. Facilities that have a high proportion of patients with adequate small solute clearance may also have processes of care in place that would likely avoid hospitalization. In addition, patients who are unable to achieve a Kt/V of 1.2 may be morbidly obese, use a catheter for vascular access, or be non-adherent to treatment recommendations such that they may be at higher risk for hospitalization. Higher rates of the facility level percentage of patients with adequate dialysis (facility percentage Kt/V≥ 1.2) will be negatively associated with SHR.

Positive Relationships

- Vascular Access: Long-term catheter rate (catheter in use >=3 continuous months) – We expect a positive association between long-term catheter rate and SHR. Long-term catheters put patients at increased risk for infection and other complications. Additionally, a high long-term catheter rate also indicates a higher patient comorbidity burden at the facility level such that sicker patients who have a long-term catheter may also be more likely to be admitted to the hospital. Higher long-term catheter rates will be positively associated with SHR.
- SMR: We expect a positive association with SHR. Patients who require acute inpatient medical care represent an at-risk population for mortality since they likely have greater acute medical needs or complications from chronic comorbid conditions that put them at higher risk for death. Higher SMR will be positively associated with SHR.
- SRR: We expect a positive association with SHR. Both hospitalization and readmission are a reflection of hospital utilization and increased comorbidity burden. Additionally, readmission of patients after a recent discharge indicates they still require acute inpatient medical attention or experience other post-discharge complications. Higher SRR will be positively associated with SHR.
- STrR: We expect a positive association with SHR. Patients with severe anemia may require hospitalization and blood transfusion, placing them at risk for other adverse acute medical events. Additionally, most blood transfusions occur in the in-patient setting. Higher STrR will be positively associated with SHR.

The measure is also maintained on face validity. Hospitalization measures were first reviewed by a TEP in 2007 which recommended an overall measure based on admissions and on days for inclusion in the Dialysis Facility Reports. Later the SHR was implemented on DFC for public reporting. In 2015, a TEP was held specifically to consider adding prevalent comorbidity adjustments for SHR. The TEP's recommendations are reflected in the risk adjustment methodology. In addition, hospitalization is a major cost factor in the management of ESRD patients, further establishing a very strong case for face validity of the SHR admissions measure.

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

2011 Submission

The SHR Admissions measure is correlated with the Standardized Mortality Ratio (SMR) over the three year cohort (r=0.40) and in individual years r was approximately equal to 0.33, both correlations being highly significant. In addition, SHR Admissions is negatively correlated in each of the three year with percent of patients in the facility with AV Fistula (r=-0.27, -0.23, -0.21). Thus higher values of SHR are associated with lower usage of AV Fistulas. On the other hand, SHR admissions is positively correlated with catheter use (r=0.24, 0.23, 0.22), indicating that higher values of SHR are associated with increased use of catheters. These correlations are all highly significant ($p<0.001$). The SHR Admissions is also found to be negatively correlated (r=-0.10, $p<0.0001$) with the percent of patients with URR>65, again in the direction expected.

The SHR Admissions is an overall measure of hospital use and is comprised of many different causes or reasons for hospitalization. The TEP considered the possibility of devising cause specific SHRs, but recommended the use of overall SHR measures due to various reasons including the lack of clear research to indicate what causes should be selected as indicative of poor ESRD care and issues associated with inter-rater reliability in assessing cause of hospitalization. The TEP reached a strong consensus that the overall measures should give a reliable and valid measure that would typically be related to quality of care. We have some crude measures of cause of hospitalization which we have taken to assess the relationship between the overall measure and cause specific components. These measures are useful in assessing the overall SHR measures, but we caution that the cause specific hospitalizations have not been tested or validated at this time. The overall SHR Admissions is strongly correlated with the SHR for cause specific hospitalizations. The correlation with Septicemia is r=0.44, with Chronic Heart Failure is r=0.55 and with an overall measure including Septicemia and a collection of coronary causes is r=0.66. Thus the overall hospitalization rate also correlates strongly with causes that are commonly thought to be potentially related to poor quality of care.

2016 Submission

The SHR Admissions measure is correlated with the Standardized Mortality Ratio (SMR) for each individual year from 2010-2013, where Spearman's correlation coefficient ranged from 0.27 to 0.30, with all four correlations being highly significant ($p<0.0001$). Also for each year from 2011-2013, the SHR

was correlated with the Standardized Readmission Ratio (SRR) (Spearman's rho=0.54, 0.50, 0.48; p<0.0001).

In addition, SHR Admissions is negatively correlated in each of the four years with percent of patients in the facility with AV Fistula (Spearman's rho= -0.12, -0.15, -0.12, -0.13). Thus higher values of SHR are associated with lower usage of AV Fistulas. Further, SHR admissions is positively correlated in each of the four years with percent of patients with catheter >= 90 days (Spearman's rho=0.21, 0.21, 0.18, 0.16), indicating that higher values of SHR are associated with increased use of catheters. These correlations are all highly significant (p<0.001). For each year of 2010 through 2013, the SHR Admissions is also found to be negatively correlated with the percent of hemodialysis patients with Kt/V>=1.2, again in the direction expected (Spearman's rho= -0.11, -0.13, -0.10,-0.11; p<0.0001). Lower SHRs are associated with a higher percentage of patients receiving adequate dialysis dose.

2019 Submission

Table 4. Correlation between SHR and other Measures, 2018

Measure	Spearman's rho	p-value
SFR	-0.16	<0.0001
Kt/V >=1.2	-0.23	<0.0001
Long-term Catheter	0.18	<0.0001
SMR	0.28	<0.0001
SRR	0.47	<0.0001
STrR	0.42	<0.0001

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

2011 Submission

This was not a question on the 2011 Submission Form.

2016 Submission

The SHR correlates with outcomes, processes of care, and causes of hospitalization that are commonly thought to be potentially related to poor quality of care. Higher hospitalization was associated with higher facility mortality rates; and similarly with higher readmissions. We found higher values of SHR are associated with lower usage of AV Fistulas, higher catheter use, and suboptimal dialysis adequacy.

The 2007 TEP considered the possibility of developing cause specific SHRs, but recommended the use of all-cause SHR measures due to various reasons including the lack of clear research to indicate what causes (i.e., reason for admission) should be selected as valid indicators of poor ESRD care, and issues associated with inter-rater reliability in assessing cause of hospitalization. The TEP reached a strong consensus that the all-cause measure would be reliable and valid and the measure would typically be

related to quality of care. We have some crude measures of cause of hospitalization which we have used to assess the relationship between the all-cause measure and cause specific components. These measures are useful in assessing the overall SHR measures, but we caution that the cause specific hospitalizations have not been tested or validated at this time. All correlations are in the expected direction and highly significant, ($p<0.0001$). Thus these preliminary analyses show that the overall hospitalization rate also correlates with specific causes that are commonly thought to be potentially related to poor quality of care. In 2015, a TEP was held specifically to consider prevalent comorbidity adjustments for inclusion in this measure (and SMR). The TEP's recommendations are reflected in the risk adjustment methodology.

2019 Submission

Hospitalization as measured by SHR has the expected correlations with outcomes and processes of care commonly thought to be related to quality of care. Higher SHR was associated with higher facility mortality rates, higher transfusion events, higher readmission, and higher long-term catheter rates. We found higher values of SHR were also associated with lower AV Fistula rates, and suboptimal dialysis adequacy.

We also maintain the measure on the basis of face validity based on the 2015 TEP.

2b2. EXCLUSIONS ANALYSIS

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

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

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

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

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

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

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

☐ **No risk adjustment or stratification**

☒ **Statistical risk model with 125 risk factors**

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

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

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

2016 Submission

The risk adjustment is based on a Cox or relative risk model. The adjustment is made for patient age, sex, diabetes, duration of ESRD, nursing home status, BMI at incidence, comorbidities at incidence, a set of prevalent comorbidities, and calendar year. In this model, covariates are taken to act multiplicatively on the admission rate and the adjustment model is fitted with facility defining strata so as to provide valid estimates even if the distribution of adjustment variables differs across facilities. Relevant references are Cox (1972), Kalbfleisch and Prentice (2002), Lawless and Nadeau (1995), Lin et al. (2000), Cook and Lawless (2007) and Liu, Schaubel and Kalbfleisch (2010). All analyses are done using SAS.

In general, adjustment factors for the SHR were selected based on several considerations. As noted above, we began with a large set of patient characteristics, including demographics, comorbidities at ESRD incidence, a set of prevalent comorbidities, and other characteristics. Factors considered appropriate were then investigated with statistical models, including interactions between sets of adjusters, to determine if they were related to hospitalizations. Factors related to the SHR were also evaluated for face validity before being included. Finally, SDS/SES factors were evaluated based on appropriateness (whether related to disparities in care), empirical association with the outcome, and as supported in published literature.

First, in 2007, a Technical Expert Panel was convened; the TEP provided advice on various aspects of the SHR, including adjustment factors. The 2007 Hospitalization TEP felt that facility characteristics are generally not appropriate for use as adjusters, but should be evaluated for their potential as proxies for patient characteristics. They also recommended that facility market characteristics, such as local hospital utilization rates, should not be considered as risk adjusters.

More recently, there has been great interest among dialysis care providers and other stakeholders in adjusting for more current (prevalent) comorbidities to reflect the current health status of dialysis patients, and specifically inclusion of conditions associated with hospitalization. In response CMS contracted with UM-KECC to convene a Technical Expert Panel (TEP) in September 2015 to consider the addition of prevalent comorbidity risk adjustment. The summary report for the TEP can be found here: https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/MMS/TechnicalExpertPanels.html. The TEP was charged with evaluating the potential of including prevalent comorbidities in the SMR and SHR risk adjustment models. Specific objectives included: (1) review of the comorbidity adjustment (determined at ESRD incidence) in the current NQF endorsed SMR and SHR measures; and (2) consideration of what, if any, prevalent comorbidities would be appropriate to include in each measure. In developing its recommendations, the TEP was asked to apply the criteria for risk-adjusters developed by the National Quality Forum (NQF): (1) Risk adjustment should be based on patient factors that influence the measured outcome and are present at the start of care; (2) Measures should not be adjusted for factors related to disparities in care or the quality of care; (3) Risk adjustment factors must be substantially related to the outcome being measured; (4) Risk adjustment factors should not reflect quality of care by the provider/facility being evaluated.

Reflecting these criteria, the TEP evaluated a list of prevalent comorbidities derived through the following process. First, the ESRD Hierarchical Condition Categories (ESRD-HCCs) were used as a starting point to identify ICD-9 diagnosis codes related to dialysis care. Those individual ICD-9 conditions that comprised the respective ESRD HCCs, with a prevalence of at least 0.1% in the patient population, were then selected for analysis to determine their statistical relationship to mortality and/or hospitalization. This step resulted in 555 diagnoses comorbidities (out of over 3000 ICD-9 diagnosis codes in the ESRD-HCCs). Next, an adaptive lasso variable selection method was applied to these 555 diagnoses to identify those with a statistically significant relationship to mortality and/or hospitalization ($p<0.05$). This process identified 242 diagnoses. The TEP members then scored each of these diagnoses as follows:

1. Very likely the result of dialysis facility care
2. Likely the result of dialysis facility care
3. May or may not be the result of dialysis facility care
4. Unlikely to be the result of dialysis facility care
5. Very likely not the result of dialysis facility care

This scoring exercise aimed at identifying a set of prevalent comorbidities not likely the result of facility care and therefore potentially appropriate as risk adjusters for SHR and SMR. The TEP established that comorbidities scored as "unlikely" or "very unlikely the result of facility care" by at least half of TEP members (simple majority) were judged as appropriate for inclusion as risk-adjusters. This process resulted in 210 conditions as risk adjustors. The TEP further recommended that: (1) comorbidities for inclusion as risk-adjusters in a particular year should be present in Medicare claims in the preceding calendar year; and (2) determination of a prevalent comorbidity required at least two outpatient claims or one inpatient claim. The set of prevalent comorbidities recommended by the TEP for inclusion as risk-adjusters is presented listed below.

Consideration of SDS/SES risk factors

The relationship among patient level SDS, socioeconomic disadvantage and health care utilization such as hospitalization is well-established in the general population and has received considerable attention over the years. (AHRQ Reports, 2011; 2012; 2013; 2014; 2015). The likelihood of hospitalization is related to socioeconomic disadvantage through differences in health status, insurance coverage, and access to quality primary care (Basu et al, 2012; Blustein et al, 1998). Further, individual and market or area-level measures of deprivation have been shown to contribute independently to preventable hospitalizations (Moy et al, 2013).

Health care outcomes and utilization are associated with area-level income and residential segregation, but particularly so for racial minorities (Williams, 2006 ; Williams and Collins, 2001). This suggests the interplay of patient level (race) and area level SES factors related to lower income, neighborhood poverty, segregation, levels of educational attainment, and unemployment levels that jointly influence key health outcomes related to morbidity (Williams 2006; Williams and Collins, 2001; AHRQ, 2008).

Within the dialysis population area-level SES are associated with poor outcomes (Almachraki et al 2016); while patient level factors such as race are predictive of differences in certain clinical outcomes by race. (Yan et al 2014; Whittle et al 1991). In a study of first year hemodialysis patients, patients of Hispanic

ethnicity had lowest all-cause hospital length of stay compared to whites, while patients of black race had intermediate all-cause hospital admissions that was lower relative to whites but higher than Hispanic patient, with differences observed across certain age groups (Yan et al, CJASN 2014). Moreover the study authors found that infection-related hospitalizations were significantly higher for black and Hispanic patients compared to non-Hispanic whites. These associations could indicate certain facility level practices related to effective infection control and prevention may unevenly impact patients of black race and Hispanic ethnicity (Yan et al CJASN 2014 p7).

Insurance status is also related to health outcomes but this has not been studied extensively within the dialysis population as it relates to hospitalization, though the association has been documented in studies of the general dual Medicare and Medicaid population. Dual eligibles typically have greater comorbidity burden, face access to care barriers which in turn drive higher hospital utilization (Jiang et al, 2010; Moon and Shin,2006; Wright et al., 2015).

Maintaining employment is a challenge for dialysis patients which in turn can influence well-being and may have a proximal impact on outcomes such as hospitalization (Curtin et al, AJKD 1996).

Given these observed linkages we tested these patient- and area-level SDS/SES variables based on the conceptual relationships as described above and demonstrated in the literature, as well as the availability of data for the analyses. Measures of area-level socioeconomic deprivation are included as individual components from the Area Deprivation Index (Singh, 2003).

2019 Submission

The risk adjustment is based on a Cox or relative risk model. The adjustment is made for the following variables:

- Patient age: Age (continuous); Age squared
- Sex
- Proportion of Medicare Advantage months
- Diabetes as cause of ESRD
- Nursing home status in previous 365 days:
    - None (0 days)
    - Short term (0-89 days)
    - Long term >=90 days)
- BMI at ESRD incidence
    - BMI < 18.5
    - 18.5 ≤ BMI < 25
    - 25≤ BMI < 30
    - BMI≥30
- Comorbidities at ESRD incidence
    - Atherosclerotic heart disease
    - Other cardiac disease
    - Diabetes that is not cause of ESRD (all types including diabetic retinopathy)

    - Congestive heart failure
    - Inability to ambulate
    - Chronic obstructive pulmonary disease
    - Inability to transfer
    - Malignant neoplasm, cancer
    - Peripheral vascular disease
    - Cerebrovascular disease, CVA, TIA
    - Tobacco use (current smoker)
    - Alcohol dependence
    - Drug dependence
    - No Medical Evidence (CMS-2728) Form
    - At least one of the comorbidities listed
- A set of prevalent comorbidities based on Medicare inpatient claims (individual comorbidities categorized into 90 groups – see below)
    - Includes an adjustment for less than 6 months of Medicare covered months in prior calendar year
- Calendar year
- Beside main effects, two-way interaction terms between age, sex, and cause of ESRD are also included:

    - Diabetes as cause of ESRD*Sex
    - Diabetes as cause of ESRD*Age
    - Age*Sex

In this model, covariates are taken to act multiplicatively on the admission rate and the adjustment model is fitted with facility defining strata so as to provide valid estimates even if the distribution of adjustment variables differs across facilities. Relevant references are Cox (1972), Kalbfleisch and Prentice (2002), Lawless and Nadeau (1995), Lin et al. (2000), Cook and Lawless (2007) and Liu, Schaubel and Kalbfleisch (2010). All analyses are done using SAS. In general, adjustment factors for the SHR were selected based on several considerations. As noted above, we began with a large set of patient characteristics, including demographics, comorbidities at ESRD incidence, a set of prevalent comorbidities, and other characteristics. Factors considered appropriate were then investigated with statistical models, including interactions between sets of adjusters, to determine if they were related to hospitalizations. Factors related to the SHR were also evaluated for face validity before being included. We also made refinements to the nursing home indicator, splitting it into two indicators representing long-term and short term nursing home stays in the prior 365 days. This granularity better accounts for the sicker and higher risk population requiring longer term skilled nursing home care. Age, previously a categorical covariate, was transformed into a quadratic functional form to better estimate the age specific effects on risk of hospital admission. We also include age as a linear variable.

In 2007, a Technical Expert Panel was convened; the TEP provided advice on various aspects of the SHR, including adjustment factors. The 2007 Hospitalization TEP felt that facility characteristics are generally not appropriate for use as adjusters, but should be evaluated for their potential as proxies for patient

characteristics. The TEP also recommended that facility market characteristics, such as local hospital utilization rates, should not be considered as risk adjusters.

In 2015, CMS contracted with UM-KECC to convene an additional Technical Expert Panel (TEP) to consider the addition of prevalent comorbidities in the SMR and SHR risk adjustment models. The summary report for the TEP can be found here: https://dialysisdata.org/content/esrd-measuresSpecific objectives of this TEP and a detailed description of the evaluation process and criteria for identifying appropriate comorbidities for adjustment are provided above.

This process resulted in the TEP recommending a list of 210 conditions for inclusion as risk adjustors. The TEP further recommended that: (1) comorbidities for inclusion as risk-adjusters in a particular year should be present in Medicare claims in the preceding calendar year; and (2) determination of a prevalent comorbidity required at least two outpatient claims or one inpatient claim. With the expansion of diagnostic codes that accompanied the transition from ICD-9 to ICD-10 in 2015, the original list of 210 comorbidities grew to over 1000 ICD-10 codes. For this 2019 submission we collapsed the 210 individual ICD-9 codes into 90 clinical groups using the AHRQ CCS categories as the framework for grouping the selected prevalent comorbidities. Using a crosswalk, the ICD-10 codes were then mapped to the 90 clinical comorbidity groups that are included in the SHR risk adjustment model (comorbidity groups are listed in the model results table in the section below). The decision to group the comorbidities was to achieve greater model parsimony.

Ascertainment of prevalent comorbidities is now restricted to identification based on inpatient Medicare claims only (previously both inpatient and outpatient claims were used).

Because all Medicare patients, including those covered by Medicare Advantage, are included in the SHR calculation, outpatient claims (which are not available for Medicare Advantage patients) are not considered in the identification of comorbidity conditions. Therefore we restrict comorbidity ascertainment to inpatient claims (as noted earlier).

A patient is considered to have a particular prevalent comorbid condition if one of the ICD10 codes for that condition (see Appendix for list of codes) appears on an inpatient claim for the patient in the prior year. If no such claim is found, the patient is considered to not have the condition. If a patient has less than 6 months of Medicare coverage in the prior year, we consider the prevalent comorbidity information to be missing. This requirement is intended to allow us to distinguish between a patient who does not have a particular comorbidity from one who does not have inpatient claims during enough of the year to determine whether the condition is present or not. An indicator is included in the model to identify these patients and all comorbid conditions are set to ‘not present’.

We also made refinements to the nursing home indicator, splitting it into two indicators representing long-term and short term nursing home stays in the prior 365 days. This revision better accounts for the sicker and higher risk population requiring longer term skilled nursing home care.

Finally, SDS/SES factors were evaluated based on appropriateness (whether related to disparities in care), empirical association with the outcome, and as supported in published literature (see section 2b3.3b)

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

N/A

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

2019 submission: See 2b3.1.1 above for description of selection of patient risk factors.

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

- ☒ **Published literature**
- ☒ **Internal data analysis**
- ☐ **Other (please describe)**

The relationship among patient level SDS, socioeconomic disadvantage and health care utilization such as hospitalization is well-established in the general population and has received considerable attention over the years. (AHRQ Reports, 2011; 2012; 2013; 2014; 2015). The likelihood of hospitalization is related to socioeconomic disadvantage through differences in health status, insurance coverage, and access to quality primary care (Basu et al, 2012; Blustein et al, 1998). Further, individual and market or area-level measures of deprivation have been shown to contribute independently to preventable hospitalizations (Moy et al, 2013).

Health care outcomes and utilization are associated with area-level income and residential segregation, but particularly so for racial minorities (Williams, 2006; Williams and Collins, 2001). This suggests the interplay of patient level (race) and area level SES factors related to lower income, neighborhood poverty, segregation, levels of educational attainment, and unemployment levels that jointly influence key health outcomes related to morbidity (Williams 2006; Williams and Collins, 2001; AHRQ, 2008).

Within the dialysis population area-level SES are associated with poor outcomes (Almachraki et al 2016); while patient level factors such as race are predictive of differences in certain clinical outcomes by race. (Yan et al 2014; Whittle et al 1991). In a study of first year hemodialysis patients, patients of Hispanic

ethnicity had lowest all-cause hospital length of stay compared to whites, while patients of black race had intermediate all-cause hospital admissions that was lower relative to whites but higher than Hispanic patient, with differences observed across certain age groups (Yan et al, CJASN 2014). Moreover the study authors found that infection-related hospitalizations were significantly higher for black and Hispanic patients compared to non-Hispanic whites. These associations could indicate certain facility level practices related to effective infection control and prevention may unevenly impact patients of black race and Hispanic ethnicity (Yan et al CJASN 2014 p7).

Insurance status is also related to health outcomes but this has not been studied extensively within the dialysis population as it relates to hospitalization, though the association has been documented in studies of the general dual Medicare and Medicaid population. Dual eligibles typically have greater comorbidity burden, face access to care barriers which in turn drive higher hospital utilization (Jiang et al, 2010; Moon and Shin,2006; Wright et al., 2015).

Maintaining employment is a challenge for dialysis patients which in turn can influence well-being and may have a proximal impact on outcomes such as hospitalization (Curtin et al, AJKD 1996).

As described in the previous submission, the relationship among patient level SDS, socioeconomic disadvantage and health care utilization such as hospitalization is well-established in the general population and has received considerable attention over the years. Given these observed linkages we tested these patient- and area-level SDS/SES variables based on the conceptual relationships as described above and demonstrated in the literature, as well as the availability of data for the analyses. In total, we tested the following variables:

Patient level:

- Employment status 6 months prior to ESRD
- Sex
- Race
- Ethnicity
- Medicare dual eligible
- ZIP code level – Area Deprivation Index (ADI) from Census data (2009-2013). Based on patient zip-code. We use the publicly available Area Deprivation Index (ADI) originally developed by Singh and colleagues at the University of Wisconsin. We applied the updated ADI based on 2009-2013 census data (University of Wisconsin, 2013 v1.5). The ADI reflects a full set of SES characteristics, including measures of income, education, and employment status, measured at the ZIP code level.

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

2016 Submission

Table 2a. Model Coefficients, Data Years 2010–2013.

Covariate	Coefficient	P-value
Comorbidities at start of ESRD		
At least one of the comorbidities listed below	0.08624	<.0001
Atherosclerotic heart disease	0.04999	<.0001
Other cardiac disease	0.04395	<.0001
Diabetes*	-0.02026	<.0001
Congestive heart failure	0.04269	<.0001
Inability to ambulate	0.02042	<.0001
Chronic obstructive pulmonary disease	0.05646	<.0001
Inability to transfer	0.02401	<.0001
Malignant neoplasm, cancer	0.04102	<.0001
Peripheral vascular disease	0.04104	<.0001
Cerebrovascular disease, CVA, TIA	0.01904	<.0001
Tobacco use (current smoker)	0.08539	<.0001
Alcohol dependence	0.01285	0.036
Drug dependence	0.17361	<.0001
No Medical Evidence (CMS-2728) Form	0.15316	<.0001
Cause of ESRD		
Diabetes	0.03848	<.0001
Missing	-0.03547	<.0001
Sex: Female	0.07156	<.0001
Age		
0-14	0.48884	<.0001
15-24	0.13135	<.0001
25-44	-0.0678	<.0001

Covariate	Coefficient	P-value
45-59	-0.065	<.0001
60-74	Reference	
75+	0.10178	<.0001
BMI		
Log BMI	-0.15032	<.0001
BMI missing	0.01656	0.0002
Calendar year		
2010	Reference	
2011	-0.02546	<.0001
2012	-0.12676	<.0001
2013	-0.16265	<.0001
In nursing home the previous year	0.20788	<.0001
Diabetes as cause of ESRD X time on ESRD interaction term		
91 days-6 months	Reference	
6 months-1 year	0.03417	<.0001
1-2 years	0.01166	0.0737
2-3 years	0.00139	0.8356
3-5 years	-0.01549	0.0147
5+ years	-0.06398	<.0001
Cause of ESRD: diabetes X sex: female interaction term	-0.02622	<.0001
Age X diabetes as cause of ESRD interaction term		
0-14	-0.93749	<.0001
15-24	0.16727	<.0001
25-44	0.15502	<.0001
45-59	0.05013	<.0001
60-74	Reference	

Covariate	Coefficient	P-value
75+	-0.03426	<.0001
Age X female sex interaction term		
0-14	-0.13038	0.0002
15-24	0.24562	<.0001
25-44	0.12877	<.0001
45-59	0.03139	<.0001
60-74	Reference	
75+	-0.00664	0.0685

*The diabetes indicator includes all diabetes comorbidities on CMS-2728 and diabetes as cause of ESRD

Table 2b. Prevalent Comorbidity Coefficients, Data Years 2010–2013.

ICD-9 Description	ICD-9 Code	Coefficient	P-value
Sarcoidosis	135	0.0624	<.0001
Malign neopl prostate	185	-0.03133	<.0001
Malign neopl thyroid	193	-0.04837	0.0087
Oth severe malnutrition	262	0.0382	<.0001
Chr airway obstruct NEC	496	0.1908	<.0001
Postinflam pulm fibrosis	515	0.11769	<.0001
Malignant neopl rectum	1541	0.1335	<.0001
Mal neo liver, primary	1550	0.12225	<.0001
Mal neo upper lobe lung	1623	0.08088	<.0001
Mal neo bronch/lung NOS	1629	0.13617	<.0001
Malig neo bladder NOS	1889	0.10792	<.0001
Malig neopl kidney	1890	0.02548	0.0004
Secondary malig neo lung	1970	0.17282	<.0001
Second malig neo liver	1977	0.38071	<.0001
Secondary malig neo bone	1985	0.29043	<.0001
Malignant neoplasm NOS	1991	0.13518	<.0001
Protein-cal malnutr NOS	2639	0.10345	<.0001
Dis urea cycle metabol	2706	0.06036	0.0002
Senile dementia uncomp	2900	-0.02563	0.0001
Drug withdrawal	2920	0.26748	<.0001
Mental disor NEC oth dis	2948	0.04058	<.0001
Cereb degeneration NOS	3319	0.08582	<.0001
Aut neuropthy in oth dis	3371	0.02621	<.0001
Grand mal status	3453	0.01548	0.1722
Anoxic brain damage	3481	-0.03408	0.0008
Cerebral edema	3485	0.09181	<.0001
Idio periph neurpthy NOS	3569	0.09859	<.0001
Neuropathy in diabetes	3572	0.04133	<.0001
Intermed coronary synd	4111	0.2052	<.0001
Angina pectoris NEC/NOS	4139	0.12568	<.0001
Prim pulm hypertension	4160	-0.01251	0.0316
Chr pulmon heart dis NEC	4168	0.15189	<.0001
Prim cardiomyopathy NEC	4254	0.16394	<.0001
Cardiomyopath in oth dis	4258	0.16331	<.0001
Atriovent block complete	4260	0.02671	0.0001
Parox ventric tachycard	4271	0.09607	<.0001
Parox tachycardia NOS	4272	0.06145	<.0001
Subdural hemorrhage	4321	0.03408	0.0004
Aortic atherosclerosis	4400	0.09852	<.0001

ICD-9 Description	ICD-9 Code	Coefficient	P-value
Lower extremity aneurysm	4423	0.10898	<.0001
Periph vascular dis NOS	4439	0.09731	<.0001
Stricture of artery	4471	0.00238	0.6534
Oth inf vena cava thromb	4532	0.2153	<.0001
Emphysema NEC	4928	0.05787	<.0001
Bronchiectas w/o ac exac	4940	0.06175	<.0001
Food/vomit pneumonitis	5070	0.05726	<.0001
Lung involv in oth dis	5178	0.17403	<.0001
Regional enteritis NOS	5559	0.17154	<.0001
Ulceratve colitis unspcf	5569	0.06821	<.0001
Chr vasc insuff intest	5571	0.15765	<.0001
Paralytic ileus	5601	0.10245	<.0001
Intestinal obstruct NOS	5609	0.10671	<.0001
Alcohol cirrhosis liver	5712	0.05621	<.0001
Cirrhosis of liver NOS	5715	0.20344	<.0001
Hepatic encephalopathy	5722	0.17945	<.0001
Portal hypertension	5723	0.20086	<.0001
Oth sequela, chr liv dis	5728	0.14523	<.0001
Chronic pancreatitis	5771	0.38153	<.0001
Chronic skin ulcer NEC	7078	0.07843	<.0001
Syst lupus erythematosus	7100	0.24781	<.0001
Systemic sclerosis	7101	0.12899	<.0001
Rheumatoid arthritis	7140	0.10921	<.0001
Inflamm polyarthrop NOS	7149	0.02641	0.1369
Sacroiliitis NEC	7202	0.16649	<.0001
Gangrene	7854	0.05466	<.0001
Cachexia	7994	0.14375	<.0001
Fracture of pubis-closed	8082	0.06248	<.0001
Pelvic fracture NOS-clos	8088	-0.01048	0.4819
Fx neck of femur NOS-cl	8208	-0.02685	<.0001
Amput below knee, unilat	8970	-0.10393	<.0001
Amputat bk, unilat-compl	8971	-0.10582	<.0001
Amput above knee, unilat	8972	-0.08573	<.0001
Amputat leg, unilat NOS	8974	-0.077	<.0001
Candidal esophagitis	11284	0.1985	<.0001
Oth lymp unsp xtrndl org	20280	0.14363	<.0001
Mult mye w/o achv rmson	20300	0.19204	<.0001
Ch lym leuk wo achv rmsn	20410	0.25565	<.0001
Essntial thrombocythemia	23871	0.10421	<.0001
Low grde myelody syn les	23872	0.14376	<.0001

ICD-9 Description	ICD-9 Code	Coefficient	P-value
Myelodysplastic synd NOS	23875	0.17806	<.0001
DMII wo cmp nt st uncntr	25000	0.11986	<.0001
DMII wo cmp uncntrld	25002	0.02111	<.0001
DMII keto nt st uncntrld	25010	0.03729	<.0001
DMII ketoacd uncontrold	25012	0.13424	<.0001
DMI ketoacd uncontrold	25013	0.25355	<.0001
DMII hprosmlr uncontrold	25022	0.12376	<.0001
DMII renl nt st uncntrld	25040	0.0746	<.0001
DMI renl nt st uncntrld	25041	0.04644	<.0001
DMII ophth nt st uncntrl	25050	0.00743	0.0064
DMI ophth uncntrld	25053	0.05823	<.0001
DMII neuro nt st uncntrl	25060	0.05824	<.0001
DMI neuro nt st uncntrld	25061	0.04909	<.0001
DMII neuro uncntrld	25062	0.07612	<.0001
DMI neuro uncntrld	25063	0.13715	<.0001
DMII circ nt st uncntrld	25070	-0.04017	<.0001
DMI circ nt st uncntrld	25071	-0.05298	<.0001
DMII circ uncntrld	25072	-0.02251	<.0001
DMII oth nt st uncntrld	25080	0.08205	<.0001
DMI oth nt st uncntrld	25081	0.02286	0.0002
DMII oth uncntrld	25082	0.03781	<.0001
DMI oth uncntrld	25083	0.00729	0.3939
Glucocorticoid deficient	25541	0.17576	<.0001
Amyloidosis NEC	27739	0.15827	<.0001
Metabolism disorder NEC	27789	0.21983	<.0001
Morbid obesity	27801	0.07927	<.0001
Obesity hypovent synd	27803	-0.05432	<.0001
Sickle cell disease NOS	28260	0.71791	<.0001
Antin chemo indcd pancyt	28411	0.10449	0.0005
Other pancytopenia	28419	0.1945	<.0001
Neutropenia NOS	28800	0.16551	<.0001
Drug induced neutropenia	28803	0.14431	<.0001
Prim hypercoagulable st	28981	0.18562	<.0001
Senile delusion	29020	-0.11382	<.0001
Vascular dementia,uncomp	29040	-0.00174	0.8249
Dementia w/o behav dist	29410	0.01212	0.0613
Dementia w behavior dist	29411	-0.02334	0.0177
Demen NOS w/o behv dstrb	29420	0.04516	<.0001
Schizophrenia NOS-unspec	29590	0.15532	<.0001
Depress psychosis-unspec	29620	0.17524	<.0001

ICD-9 Description	ICD-9 Code	Coefficient	P-value
Recurr depr psychos-unsp	29630	0.08526	<.0001
Recur depr psych-severe	29633	0.07789	<.0001
Bipolar disorder NOS	29680	0.19198	<.0001
Bipolar disorder NEC	29689	0.08524	<.0001
Episodic mood disord NOS	29690	0.07786	<.0001
Alcoh dep NEC/NOS-unspec	30390	0.16788	<.0001
Alcoh dep NEC/NOS-remiss	30393	0.07322	<.0001
Opioid dependence-unspec	30400	0.25245	<.0001
Opioid dependence-contin	30401	0.18003	<.0001
Drug depend NOS-unspec	30490	0.27902	<.0001
Psymotr epil w/o int epi	34540	-0.08114	<.0001
Epilep NOS w/o intr epil	34590	0.19176	<.0001
Critical illness myopthy	35981	-0.09196	<.0001
Prolif diab retinopathy	36202	-0.08631	<.0001
Mod nonprolf db retinoph	36205	-0.07697	<.0001
Diabetic macular edema	36207	-0.0601	<.0001
Hyp ht dis NOS w ht fail	40291	0.03839	<.0001
Subendo infarct, initial	41071	0.18348	<.0001
AMI NEC, unspecified	41080	0.03986	0.0367
AMI NOS, unspecified	41090	-0.03149	<.0001
Ac ischemic hrt dis NEC	41189	0.11644	<.0001
Pulm embol/infarct NEC	41519	0.13237	<.0001
Atrial fibrillation	42731	0.13302	<.0001
Atrial flutter	42732	0.08346	<.0001
Sinoatrial node dysfunct	42781	-0.00923	0.0206
Crbl emblsm w infrct	43411	0.01754	0.0772
Crbl art ocl NOS w infrc	43491	0.07113	<.0001
Athscl extrm ntv art NOS	44020	0.00141	0.6632
Ath ext ntv at w claudct	44021	0.04379	<.0001
Ath ext ntv at w rst pn	44022	0.09607	<.0001
Ath ext ntv art ulcrtion	44023	0.02268	<.0001
Dsct of thoracic aorta	44101	0.23712	<.0001
Periph vascular dis NEC	44389	0.01881	0.0012
Deep phlebitis-leg NEC	45119	0.00269	0.7906
Ac DVT/emb prox low ext	45341	0.12676	<.0001
Ch DVT/embl low ext NOS	45350	0.12558	<.0001
Ch DVT/embl prox low ext	45351	0.09937	<.0001
Ch emblsm subclav veins	45375	0.17741	<.0001
Ac DVT/embl up ext	45382	0.08862	<.0001
Ac emblsm axillary veins	45384	0.10835	<.0001

ICD-9 Description	ICD-9 Code	Coefficient	P-value
Ac embl internl jug vein	45386	0.16307	<.0001
Ac embl thorac vein NEC	45387	0.13445	<.0001
Esoph varice oth dis NOS	45621	0.19764	<.0001
Obs chr bronc w(ac) exac	49121	0.16393	<.0001
Obs chr bronc w ac bronc	49122	0.11419	<.0001
Chronic obst asthma NOS	49320	0.10527	<.0001
Ch obst asth w (ac) exac	49322	0.10999	<.0001
Ac resp flr fol trma/srg	51851	-0.04255	0.0003
Ot pul insuf fol trm/srg	51852	-0.0827	0.0003
Other pulmonary insuff	51882	0.13098	<.0001
Chronic respiratory fail	51883	0.0293	<.0001
Acute & chronc resp fail	51884	0.02507	<.0001
Gastrostomy comp - mech	53642	0.10042	<.0001
Fecal impaction	56032	0.09744	<.0001
Pressure ulcer, low back	70703	0.0362	<.0001
Pressure ulcer, hip	70704	0.09173	<.0001
Pressure ulcer, buttock	70705	0.00396	0.4043
Ulcer of lower limb NOS	70710	0.01138	0.0098
Ulcer other part of foot	70715	0.04066	<.0001
Ulcer oth part low limb	70719	0.03358	<.0001
Pyogen arthritis-unspec	71100	0.03922	0.0151
Pyogen arthritis-l/leg	71106	0.11218	<.0001
Ac osteomyelitis-unspec	73000	-0.04005	0.0005
Ac osteomyelitis-ankle	73007	-0.03799	<.0001
Ac osteomyelitis NEC	73008	-0.01851	0.102
Osteomyelitis NOS-hand	73024	0.05835	0.0001
Osteomyelitis NOS-ankle	73027	-0.03107	<.0001
Path fx vertebrae	73313	0.1329	<.0001
Aseptic necrosis femur	73342	0.20291	<.0001
Asept necrosis bone NEC	73349	0.17431	<.0001
Coma	78001	0.02143	0.1083
Convulsions NEC	78039	0.10277	<.0001
Fx femur intrcaps NEC-cl	82009	0.03652	0.0079
Fx femur NOS-closed	82100	-0.05632	<.0001
React-indwell urin cath	99664	0.15093	<.0001
Compl heart transplant	99683	0.02305	0.3552
Asymp hiv infectn status	V08	0.37403	<.0001
Heart transplant status	V421	0.26702	<.0001
Liver transplant status	V427	0.16234	<.0001
Trnspl status-pancreas	V4283	0.14978	<.0001

ICD-9 Description	ICD-9 Code	Coefficient	P-value
Gastrostomy status	V441	0.02184	0.0173
Ileostomy status	V442	0.12312	<.0001
Colostomy status	V443	0.13378	<.0001
Urinostomy status NEC	V446	0.33981	<.0001
Respirator depend status	V4611	-0.02597	0.001
Status amput othr toe(s)	V4972	0.031	<.0001
Status amput below knee	V4975	0.02473	<.0001
Status amput above knee	V4976	0.01774	0.0036
Atten to gastrostomy	V551	-0.03053	0.0012
Long-term use of insulin	V5867	0.12534	<.0001
BMI 40.0-44.9, adult	V8541	0.03116	<.0001
Less than 6 months of Medicare eligible claims in the previous calendar year		0.73799	<.0001

Most of the coefficient estimates for the prevalent comorbidities are positive and statistically significant, but several do not obtain statistical significance. The very large number of clinical factors in the model expectedly generates substantial multicollinearity among the covariates, likely resulting in some unexpected results in the direction of the coefficient sign and levels of statistical significance. Inclusion of this set of prevalent comorbidities reflects the consensus of the TEP that adjustment for all of these prevalent comorbidities, in addition to incident comorbidities, is important to reflect the current health condition of the patient in risk adjustment.

2019 Submission

See 2b3.1.1 above for description of selection of patient risk factors. Table 5 presents results for the selected clinical and patient risk factors for the baseline SHR model

Table 5. Base Model Coefficients, Data Years 2015–2018.

Covariate	Coefficient	P-value^	Hazard Ratio^
Comorbidities at start of ESRD			
At least one of the comorbidities listed below	0.068	<.0001	1.071
Atherosclerotic heart disease	0.049	<.0001	1.050
Other cardiac disease	0.044	<.0001	1.045
Diabetes (other than cause of ESRD)	-0.028	<.0001	0.972
Congestive heart failure	0.040	<.0001	1.041
Inability to ambulate	0.035	<.0001	1.036
Chronic obstructive pulmonary disease	0.070	<.0001	1.072
Inability to transfer	0.018	0.001	1.018
Malignant neoplasm, cancer	0.044	<.0001	1.045
Peripheral vascular disease	0.042	<.0001	1.043
Cerebrovascular disease, CVA, TIA	0.015	<.0001	1.015
Tobacco use (current smoker)	0.127	<.0001	1.136
Alcohol dependence	0.017	0.0058	1.017
Drug dependence	0.208	<.0001	1.231
No Medical Evidence (CMS-2728) Form	0.029	0.002	1.030
Cause of ESRD			
Diabetes	0.726	--	--
Missing	0.116	<.0001	1.123
Sex: Female	0.412	--	--
Age			
Age	-0.020	--	--
Age squared	0.00017	--	--
BMI			
BMI < 18.5	0.119	<.0001	1.126
18.5 ≤ BMI < 25	0.077	<.0001	1.080
25≤ BMI < 30	0.043	<.0001	1.044
BMI≥30	Reference	N/A	
Medicare coverage			
Proportion of months with Medicare Advantage	-0.165	<.0001	0.848
Calendar year			
2015	Reference	N/A	
2016	-0.027	<.0001	0.973

Covariate	Coefficient	P-value^	Hazard Ratio^
2017	-0.068	<.0001	0.935
2018	-0.057	<.0001	0.944
Nursing home during the prior 365 days			
No nursing home care (0 days)	Reference	N/A	
Short-term nursing home care (<90 days)	0.227	<.0001	1.255
Long-term nursing home care (>=90 days)	0.109	<.0001	1.116
Interaction: Cause of ESRD: diabetes and female sex	-0.017	<.0001	0.983
Interaction: Diabetes as cause of ESRD and			
Age	-0.019	<.0001	0.981
Age squared	0.00012	<.0001	1.000
Interaction: female sex and			
Age	-0.008	<.0001	0.992
Age squared	0.00004	<.0001	1.000
Prevalent Comorbidities (condition groups)			
Candidal esophagitis	0.184	<.0001	1.202
Sarcoidosis	0.106	<.0001	1.112
Cancer of Liver	0.278	<.0001	1.320
Cancer of Lung	0.251	<.0001	1.285
Cancer of Prostate	0.088	<.0001	1.092
Cancer of Bladder	0.220	<.0001	1.246
Cancer of Kidney	0.086	<.0001	1.090
Cancer of Bone	0.292	<.0001	1.339
Other Neoplasm	0.143	<.0001	1.153
Non-Hodgkins Lymphoma	0.176	<.0001	1.193
Multiple Myeloma	0.234	<.0001	1.264
Chronic lymphoid leukemia	0.197	<.0001	1.217
Myelodysplastic Syndrome	0.192	<.0001	1.212
Essential Thrombocytopenia	0.122	<.0001	1.130
Diabetes without complications	0.163	<.0001	1.177
Diabetes with complications	0.220	<.0001	1.246
Glucocorticoid deficiency	0.151	<.0001	1.163
Malnutrition / Cachexia	0.104	<.0001	1.110
Disorders of urea cycle metabolism	0.143	<.0001	1.154
Other amyloidosis	0.128	<.0001	1.137
Other specified disorders of metabolism	0.111	<.0001	1.117
Morbid Obesity	0.012	<.0001	1.012
Sickle-cell Anemia	0.654	<.0001	1.923
Pancytopenia	0.182	<.0001	1.200
Neutropenia	0.101	<.0001	1.107

Covariate	Coefficient	P-value^	Hazard Ratio^
Primary hypercoagulable state	0.119	<.0001	1.126
Dementia	0.043	<.0001	1.044
Substance Related Disorders	0.274	<.0001	1.315
Miscellaneous Mental Health	0.070	0.0015	1.072
Opioid Dependence	0.309	<.0001	1.362
Schizophrenia	0.142	<.0001	1.153
Cerebral degeneration, unspecified	0.044	0.0048	1.045
Peripheral autonomic neuropathy in disorders classified elsewhere	0.147	<.0001	1.158
Unspecified hereditary and idiopathic peripheral neuropathy	0.143	<.0001	1.154
Epilepsy	0.199	<.0001	1.220
Bipolar Disorder	0.231	<.0001	1.260
Major depressive affective disorder	0.208	<.0001	1.231
Mood Disorders	0.159	<.0001	1.173
Alcohol Related Disorders	0.150	<.0001	1.162
Coma	0.001	0.865	1.001
Cerebral edema	0.018	0.1571	1.019
Critical illness myopathy	-0.167	<.0001	0.846
hypertensive heart disease with heart failure	0.087	<.0001	1.091
Myocardial Infarction	0.131	<.0001	1.140
Coronary Atherosclerosis	0.180	<.0001	1.197
pulmonary embolism and infarction	0.132	<.0001	1.141
Primary pulmonary hypertension	0.092	<.0001	1.096
Pulmonary Heart Disease	0.122	<.0001	1.130
Cardiomyopathy	0.138	<.0001	1.148
Atrioventricular block, complete	-0.018	0.0223	0.982
Paroxysmal Tachycardia	0.084	<.0001	1.088
Atrial fibrillation	0.135	<.0001	1.145
Atrial flutter	0.039	<.0001	1.040
Sinoatrial node dysfunction	0.019	<.0001	1.020
Acute Cerebrovascular Disease	0.048	<.0001	1.049
Peripheral and Visceral Atherosclerosis	0.130	<.0001	1.139
Venous Thromboembolism	0.145	<.0001	1.156
Esophageal varices	0.219	<.0001	1.245
Chronic Obstructive Pulmonary Disease	0.198	<.0001	1.219
Asthma	0.049	<.0001	1.050
Aspiration Pneumonitis	0.040	<.0001	1.041
Other Lower Respiratory Diseases	0.130	<.0001	1.139
Respiratory Failure	0.139	<.0001	1.149
Enteritis and Ulcerative Colitis	0.133	<.0001	1.143

Covariate	Coefficient	P-value^	Hazard Ratio^
Ileus and Intestinal Obstruction	0.099	<.0001	1.104
Cirrhosis of Liver	0.207	<.0001	1.230
Other Liver Disease	0.202	<.0001	1.223
Pancreatitis	0.337	<.0001	1.401
Chronic Skin Ulcer	0.086	<.0001	1.089
Systemic lupus erythematosus and connective tissue disorders	0.240	<.0001	1.271
Infective arthritis and osteomyelitis	-0.031	<.0001	0.969
Rheumatoid Arthritis	0.135	<.0001	1.144
Pathologic Fracture	0.131	<.0001	1.140
Aseptic Necrosis	0.154	<.0001	1.166
Hip and Femur Fracture	-0.053	<.0001	0.948
Gangrene	0.018	<.0001	1.019
Infection due to urinary catheter	0.101	<.0001	1.106
HIV	0.339	<.0001	1.404
Solid Organ Transplant	0.140	<.0001	1.150
Gastrostomy status	0.064	<.0001	1.066
Ileostomy / Colostomy Status	0.168	<.0001	1.183
Other artificial opening of urinary tract status	0.261	<.0001	1.298
Dependence on respirator, status	-0.103	<.0001	0.902
Other toe(s) amputation status	0.072	<.0001	1.075
Below knee amputation status	-0.009	0.025	0.991
Above knee amputation status	0.017	0.0031	1.017
Long-term (current) use of insulin	0.102	<.0001	1.108
Cancer of Rectum	0.113	<.0001	1.120
Inflammatory polyarthropathy	0.261	<.0001	1.299
Sacroiliitis	0.182	<.0001	1.200
Less than 6 months of Medicare covered months in prior calendar year	0.478	<.0001	1.612

^Interpretation of covariate main effects that are also included in interaction terms is not straightforward. Because of this coefficient p-values and HRs are not reported for the main effect covariates. Interaction terms can be interpreted directly. For example, the interaction between female sex and age means that the effect of female depends on age.

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

2016 Submission

The tables below show the parameter estimates for patient- and area-level SDS/SES variables based on a Cox model for hospital admissions that included these variables along with the original covariates adjusted for in SHR.

Table 3a. Comparing coefficients between sensitivity models with and without SDS/SES adjustors, 2010-2013: Model coefficients

	Baseline SHR		SDS/SES-adjusted SHR	
Covariate	**Coefficient**	**P-value**	**Coefficient**	**P-value**
Medicare coverage*				
Medicare primary + Medicaid	NA	NA	0.07628	<.0001
Medicare primary + no Medicaid	NA	NA	Reference	-
Medicare secondary/HMO	NA	NA	0.97671	<.0001
Employment status 6 months prior to ESRD				
Unemployed	NA	NA	Reference	-
Employed	NA	NA	0.05164	<.0001
Other/Unknown	NA	NA	0.02001	<.0001
Race				
White	NA	NA	Reference	-
Native American/Alaskan Native	NA	NA	-0.03346	<.0001
Asian/Pacific Islander	NA	NA	-0.20491	<.0001
Black	NA	NA	-0.06702	<.0001
Other/Unknown	NA	NA	0.01116	0.1526
Ethnicity				
Hispanic	NA	NA	-0.08082	<.0001
Non-Hispanic	NA	NA	Reference	-
Unknown	NA	NA	-0.05751	<.0001
ADI element				
Home value (median)	NA	NA	0.00208	0.2466
Family income (median)	NA	NA	-0.00197	0.0188
Income disparity**	NA	NA	-0.00118	0.0428
Monthly mortgage (median)	NA	NA	0.00029	0.9517
< 9 years of education (%)	NA	NA	-0.00124	<.0001
No high school diploma (%)	NA	NA	0.00186	<.0001
Home ownership rate (%)	NA	NA	-0.00056	<.0001
Families below the poverty level (%)	NA	NA	0.00061	0.0019
Gross rent (median)	NA	NA	0.01567	0.0081
Single-parent households with children <18 (%)	NA	NA	-0.00017	0.2071
Unemployment rate	NA	NA	0.00157	0.0001
Comorbidities at start of ESRD				
At least one of the comorbidities listed below	0.08624	<.0001	0.07638	<.0001
Atherosclerotic heart disease	0.04999	<.0001	0.04289	<.0001
Other cardiac disease	0.04395	<.0001	0.03238	<.0001
Diabetes***	-0.02026	<.0001	-0.04055	<.0001
Congestive heart failure	0.04269	<.0001	0.03675	<.0001
Inability to ambulate	0.02042	<.0001	0.01702	<.0001
Chronic obstructive pulmonary disease	0.05646	<.0001	0.04056	<.0001
Inability to transfer	0.02401	<.0001	0.02181	0.0002
Malignant neoplasm, cancer	0.04102	<.0001	0.03391	<.0001
Peripheral vascular disease	0.04104	<.0001	0.02916	<.0001
Cerebrovascular disease, CVA, TIA	0.01904	<.0001	0.01454	<.0001
Tobacco use (current smoker)	0.08539	<.0001	0.08095	<.0001

Covariate	Baseline SHR		SDS/SES-adjusted SHR	
	Coefficient	P-value	Coefficient	P-value
Alcohol dependence	0.01285	0.036	0.01570	0.0105
Drug dependence	0.17361	<.0001	0.17165	<.0001
No Medical Evidence (CMS-2728) Form	0.15316	<.0001	0.17504	<.0001
Cause of ESRD				
Diabetes	0.03848	<.0001	0.03011	<.0001
Missing	-0.03547	<.0001	-0.04048	<.0001
Sex: Female	0.07156	<.0001	0.06285	<.0001
Age				
0-14	0.48884	<.0001	0.49754	<.0001
15-24	0.13135	<.0001	0.17018	<.0001
25-44	-0.0678	<.0001	-0.02533	<.0001
45-59	-0.065	<.0001	-0.03439	<.0001
60-74	Reference	-	Reference	-
75+	0.10178	<.0001	0.07273	<.0001
BMI				
Log BMI	-0.15032	<.0001	-0.16225	<.0001
BMI missing	0.01656	0.0002	0.01456	0.0064
Calendar year				
2010	Reference	-	Reference	-
2011	-0.02546	<.0001	-0.02546	<.0001
2012	-0.12676	<.0001	-0.12349	<.0001
2013	-0.16265	<.0001	-0.16155	<.0001
In nursing home the previous year	0.20788	<.0001	0.17739	<.0001
Diabetes as cause of ESRD X time on ESRD interaction term				
91 days-6 months	Reference	-	Reference	-
6 months-1 year	0.03417	<.0001	0.02973	<.0001
1-2 years	0.01166	0.0737	0.00827	0.2049
2-3 years	0.00139	0.8356	0.00004	0.9954
3-5 years	-0.01549	0.0147	-0.01139	0.073
5+ years	-0.06398	<.0001	-0.05036	<.0001
Cause of ESRD: diabetes X sex: female interaction term	-0.02622	<.0001	-0.02295	<.0001
Age X diabetes as cause of ESRD interaction term				
0-14	-0.93749	<.0001	-0.87713	0.0003
15-24	0.16727	<.0001	0.17698	<.0001
25-44	0.15502	<.0001	0.15213	<.0001
45-59	0.05013	<.0001	0.04798	<.0001
60-74	Reference	-	Reference	-
75+	-0.03426	<.0001	-0.03067	<.0001
Age X female sex interaction term				
0-14	-0.13038	0.0002	-0.11088	0.0019
15-24	0.24562	<.0001	0.24326	<.0001
25-44	0.12877	<.0001	0.12323	<.0001
45-59	0.03139	<.0001	0.02849	<.0001
60-74	Reference	-	Reference	-
75+	-0.00664	0.0685	-0.00662	0.0696

*Patients without Medicare coverage or with unknown coverage type were excluded from the model.

**Log(100)*(the ratio of the number of households with less than $10,000 in income to the number of households with $50,000 or more in income).

***The diabetes indicator includes all diabetes comorbidities on CMS-2728 and diabetes as cause of ESRD.

Table 3b. Comparing coefficients between sensitivity models with and without SDS/SES adjustors, 2010-2013: Prevalent comorbidity coefficients

		Baseline SHR		SDS/SES-adjusted SHR	
ICD-9 Description	ICD-9 Code	Coefficient	P-value	Coefficient	P-value
Protein-cal malnutr NOS	2639	0.10345	<.0001	0.09068	<.0001
Aut neuropthy in oth dis	3371	0.02621	<.0001	0.02174	<.0001
Epilep NOS w/o intr epil	34590	0.19176	<.0001	0.16817	<.0001
Cerebral edema	3485	0.09181	<.0001	0.07959	<.0001
Subendo infarct, initial	41071	0.18348	<.0001	0.14855	<.0001
AMI NEC, unspecified	41080	0.03986	0.0367	0.07768	<.0001
AMI NOS, unspecified	41090	-0.03149	<.0001	0.01671	0.0021
Intermed coronary synd	4111	0.2052	<.0001	0.20521	<.0001
Ac ischemic hrt dis NEC	41189	0.11644	<.0001	0.11839	<.0001
Angina pectoris NEC/NOS	4139	0.12568	<.0001	0.1392	<.0001
Cardiomyopath in oth dis	4258	0.16331	<.0001	0.16447	<.0001
Atriovent block complete	4260	0.02671	0.0001	0.03722	<.0001
Parox ventric tachycard	4271	0.09607	<.0001	0.09379	<.0001
Parox tachycardia NOS	4272	0.06145	<.0001	0.07383	<.0001
Atrial fibrillation	42731	0.13302	<.0001	0.13334	<.0001
Atrial flutter	42732	0.08346	<.0001	0.07437	<.0001
Sinoatrial node dysfunct	42781	-0.00923	0.0206	0.01865	<.0001
Subdural hemorrhage	4321	0.03408	0.0004	0.04615	<.0001
Stricture of artery	4471	0.00238	0.6534	0.02688	<.0001
Paralytic ileus	5601	0.10245	<.0001	0.09073	<.0001
Convulsions NEC	78039	0.10277	<.0001	0.11375	<.0001
Gangrene	7854	0.05466	<.0001	0.04253	<.0001
Cachexia	7994	0.14375	<.0001	0.13784	<.0001
Candidal esophagitis	11284	0.1985	<.0001	0.18944	<.0001
Sarcoidosis	135	0.0624	<.0001	0.05333	<.0001
Malignant neopl rectum	1541	0.1335	<.0001	0.1436	<.0001
Mal neo liver, primary	1550	0.12225	<.0001	0.12933	<.0001
Mal neo upper lobe lung	1623	0.08088	<.0001	0.07581	<.0001
Mal neo bronch/lung NOS	1629	0.13617	<.0001	0.15539	<.0001
Malign neopl prostate	185	-0.03133	<.0001	0.00491	0.4173
Malig neo bladder NOS	1889	0.10792	<.0001	0.12933	<.0001
Malig neopl kidney	1890	0.02548	0.0004	0.04364	<.0001
Malign neopl thyroid	193	-0.04837	0.0087	-0.02906	0.1153
Secondary malig neo lung	1970	0.17282	<.0001	0.15946	<.0001
Second malig neo liver	1977	0.38071	<.0001	0.3608	<.0001
Secondary malig neo bone	1985	0.29043	<.0001	0.29427	<.0001
Malignant neoplasm NOS	1991	0.13518	<.0001	0.14138	<.0001
Oth lymp unsp xtrndl org	20280	0.14363	<.0001	0.1379	<.0001
Mult mye w/o achv rmson	20300	0.19204	<.0001	0.19396	<.0001
Ch lym leuk wo achv rmsn	20410	0.25565	<.0001	0.23055	<.0001
Essntial thrombocythemia	23871	0.10421	<.0001	0.09762	<.0001
Low grde myelody syn les	23872	0.14376	<.0001	0.16016	<.0001
Myelodysplastic synd NOS	23875	0.17806	<.0001	0.17918	<.0001
DMII wo cmp nt st uncntr	25000	0.11986	<.0001	0.15129	<.0001
DMII wo cmp uncntrld	25002	0.02111	<.0001	0.04779	<.0001
DMII keto nt st uncntrld	25010	0.03729	<.0001	0.08276	<.0001
DMII ketoacd uncontrold	25012	0.13424	<.0001	0.11517	<.0001
DMI ketoacd uncontrold	25013	0.25355	<.0001	0.20779	<.0001
DMII hprosmlr uncontrold	25022	0.12376	<.0001	0.10357	<.0001
DMII renl nt st uncntrld	25040	0.0746	<.0001	0.07666	<.0001

ICD-9 Description	ICD-9 Code	Baseline SHR		SDS/SES-adjusted SHR	
		Coefficient	P-value	Coefficient	P-value
DMI renl nt st uncntrld	25041	0.04644	<.0001	0.052	<.0001
DMII ophth nt st uncntrl	25050	0.00743	0.0064	0.00591	0.0305
DMI ophth uncntrld	25053	0.05823	<.0001	0.04352	<.0001
DMII neuro nt st uncntrl	25060	0.05824	<.0001	0.06459	<.0001
DMI neuro nt st uncntrld	25061	0.04909	<.0001	0.05464	<.0001
DMII neuro uncntrld	25062	0.07612	<.0001	0.07231	<.0001
DMI neuro uncntrld	25063	0.13715	<.0001	0.12346	<.0001
DMII circ nt st uncntrld	25070	-0.04017	<.0001	-0.02883	<.0001
DMI circ nt st uncntrld	25071	-0.05298	<.0001	-0.03436	<.0001
DMII circ uncntrld	25072	-0.02251	<.0001	-0.01743	0.0015
DMII oth nt st uncntrld	25080	0.08205	<.0001	0.07395	<.0001
DMI oth nt st uncntrld	25081	0.02286	0.0002	0.02003	0.0012
DMII oth uncntrld	25082	0.03781	<.0001	0.03026	<.0001
DMI oth uncntrld	25083	0.00729	0.3939	0.00901	0.2922
Glucocorticoid deficient	25541	0.17576	<.0001	0.16647	<.0001
Oth severe malnutrition	262	0.0382	<.0001	0.02159	0.0003
Dis urea cycle metabol	2706	0.06036	0.0002	0.06852	<.0001
Amyloidosis NEC	27739	0.15827	<.0001	0.14513	<.0001
Metabolism disorder NEC	27789	0.21983	<.0001	0.21405	<.0001
Morbid obesity	27801	0.07927	<.0001	0.06141	<.0001
Obesity hypovent synd	27803	-0.05432	<.0001	-0.06425	<.0001
Sickle cell disease NOS	28260	0.71791	<.0001	0.69038	<.0001
Antin chemo indcd pancyt	28411	0.10449	0.0005	0.08143	0.007
Other pancytopenia	28419	0.1945	<.0001	0.18252	<.0001
Neutropenia NOS	28800	0.16551	<.0001	0.1658	<.0001
Drug induced neutropenia	28803	0.14431	<.0001	0.14311	<.0001
Prim hypercoagulable st	28981	0.18562	<.0001	0.17246	<.0001
Senile dementia uncomp	2900	-0.02563	0.0001	0.00253	0.708
Senile delusion	29020	-0.11382	<.0001	-0.0962	<.0001
Vascular dementia,uncomp	29040	-0.00174	0.8249	0.00329	0.6754
Drug withdrawal	2920	0.26748	<.0001	0.2474	<.0001
Dementia w/o behav dist	29410	0.01212	0.0613	0.02147	0.0009
Dementia w behavior dist	29411	-0.02334	0.0177	-0.00281	0.7757
Demen NOS w/o behv dstrb	29420	0.04516	<.0001	0.04207	<.0001
Mental disor NEC oth dis	2948	0.04058	<.0001	0.0466	<.0001
Schizophrenia NOS-unspec	29590	0.15532	<.0001	0.15092	<.0001
Depress psychosis-unspec	29620	0.17524	<.0001	0.1634	<.0001
Recurr depr psychos-unsp	29630	0.08526	<.0001	0.0741	<.0001
Recur depr psych-severe	29633	0.07789	<.0001	0.08623	<.0001
Bipolar disorder NOS	29680	0.19198	<.0001	0.16867	<.0001
Bipolar disorder NEC	29689	0.08524	<.0001	0.08315	<.0001
Episodic mood disord NOS	29690	0.07786	<.0001	0.0807	<.0001
Alcoh dep NEC/NOS-unspec	30390	0.16788	<.0001	0.15674	<.0001
Alcoh dep NEC/NOS-remiss	30393	0.07322	<.0001	0.05354	<.0001
Opioid dependence-unspec	30400	0.25245	<.0001	0.23688	<.0001
Opioid dependence-contin	30401	0.18003	<.0001	0.1673	<.0001
Drug depend NOS-unspec	30490	0.27902	<.0001	0.27214	<.0001
Cereb degeneration NOS	3319	0.08582	<.0001	0.11595	<.0001
Grand mal status	3453	0.01548	0.1722	0.01564	0.1675
Psymotr epil w/o int epi	34540	-0.08114	<.0001	-0.06901	<.0001
Anoxic brain damage	3481	-0.03408	0.0008	-0.03967	0.0001
Idio periph neurpthy NOS	3569	0.09859	<.0001	0.10174	<.0001
Neuropathy in diabetes	3572	0.04133	<.0001	0.02274	<.0001
Critical illness myopthy	35981	-0.09196	<.0001	-0.08218	<.0001

ICD-9 Description	ICD-9 Code	Baseline SHR		SDS/SES-adjusted SHR	
		Coefficient	P-value	Coefficient	P-value
Prolif diab retinopathy	36202	-0.08631	<.0001	-0.06471	<.0001
Mod nonprolf db retinoph	36205	-0.07697	<.0001	-0.0567	<.0001
Diabetic macular edema	36207	-0.0601	<.0001	-0.04416	<.0001
Hyp ht dis NOS w ht fail	40291	0.03839	<.0001	0.05711	<.0001
Pulm embol/infarct NEC	41519	0.13237	<.0001	0.13027	<.0001
Prim pulm hypertension	4160	-0.01251	0.0316	0.02908	<.0001
Chr pulmon heart dis NEC	4168	0.15189	<.0001	0.13335	<.0001
Prim cardiomyopathy NEC	4254	0.16394	<.0001	0.15779	<.0001
Crbl emblsm w infrct	43411	0.01754	0.0772	0.01317	0.1847
Crbl art ocl NOS w infrc	43491	0.07113	<.0001	0.07869	<.0001
Aortic atherosclerosis	4400	0.09852	<.0001	0.08793	<.0001
Athscl extrm ntv art NOS	44020	0.00141	0.6632	0.01909	<.0001
Ath ext ntv at w claudct	44021	0.04379	<.0001	0.06012	<.0001
Ath ext ntv at w rst pn	44022	0.09607	<.0001	0.09649	<.0001
Ath ext ntv art ulcrtion	44023	0.02268	<.0001	0.03187	<.0001
Dsct of thoracic aorta	44101	0.23712	<.0001	0.24884	<.0001
Lower extremity aneurysm	4423	0.10898	<.0001	0.10403	<.0001
Periph vascular dis NEC	44389	0.01881	0.0012	0.02819	<.0001
Periph vascular dis NOS	4439	0.09731	<.0001	0.10228	<.0001
Deep phlebitis-leg NEC	45119	0.00269	0.7906	0.03874	0.0001
Oth inf vena cava thromb	4532	0.2153	<.0001	0.20467	<.0001
Ac DVT/emb prox low ext	45341	0.12676	<.0001	0.10691	<.0001
Ch DVT/embl low ext NOS	45350	0.12558	<.0001	0.11544	<.0001
Ch DVT/embl prox low ext	45351	0.09937	<.0001	0.09291	<.0001
Ch emblsm subclav veins	45375	0.17741	<.0001	0.17209	<.0001
Ac DVT/embl up ext	45382	0.08862	<.0001	0.08867	<.0001
Ac emblsm axillary veins	45384	0.10835	<.0001	0.09897	<.0001
Ac embl internl jug vein	45386	0.16307	<.0001	0.15905	<.0001
Ac embl thorac vein NEC	45387	0.13445	<.0001	0.1339	<.0001
Esoph varice oth dis NOS	45621	0.19764	<.0001	0.17113	<.0001
Obs chr bronc w(ac) exac	49121	0.16393	<.0001	0.15724	<.0001
Obs chr bronc w ac bronc	49122	0.11419	<.0001	0.10931	<.0001
Emphysema NEC	4928	0.05787	<.0001	0.07762	<.0001
Chronic obst asthma NOS	49320	0.10527	<.0001	0.10032	<.0001
Ch obst asth w (ac) exac	49322	0.10999	<.0001	0.10446	<.0001
Bronchiectas w/o ac exac	4940	0.06175	<.0001	0.07671	<.0001
Chr airway obstruct NEC	496	0.1908	<.0001	0.18441	<.0001
Food/vomit pneumonitis	5070	0.05726	<.0001	0.04838	<.0001
Postinflam pulm fibrosis	515	0.11769	<.0001	0.12366	<.0001
Lung involv in oth dis	5178	0.17403	<.0001	0.15417	<.0001
Ac resp flr fol trma/srg	51851	-0.04255	0.0003	-0.05125	<.0001
Ot pul insuf fol trm/srg	51852	-0.0827	0.0003	-0.0681	0.0032
Other pulmonary insuff	51882	0.13098	<.0001	0.1543	<.0001
Chronic respiratory fail	51883	0.0293	<.0001	0.0179	0.0021
Acute & chronc resp fail	51884	0.02507	<.0001	0.00683	0.1906
Gastrostomy comp - mech	53642	0.10042	<.0001	0.11609	<.0001
Regional enteritis NOS	5559	0.17154	<.0001	0.14951	<.0001
Ulceratve colitis unspcf	5569	0.06821	<.0001	0.07949	<.0001
Chr vasc insuff intest	5571	0.15765	<.0001	0.14385	<.0001
Fecal impaction	56032	0.09744	<.0001	0.09478	<.0001
Intestinal obstruct NOS	5609	0.10671	<.0001	0.11453	<.0001
Alcohol cirrhosis liver	5712	0.05621	<.0001	0.05224	<.0001
Cirrhosis of liver NOS	5715	0.20344	<.0001	0.20181	<.0001
Hepatic encephalopathy	5722	0.17945	<.0001	0.16256	<.0001

ICD-9 Description	ICD-9 Code	Baseline SHR		SDS/SES-adjusted SHR	
		Coefficient	P-value	Coefficient	P-value
Portal hypertension	5723	0.20086	<.0001	0.18288	<.0001
Oth sequela, chr liv dis	5728	0.14523	<.0001	0.14782	<.0001
Chronic pancreatitis	5771	0.38153	<.0001	0.36579	<.0001
Pressure ulcer, low back	70703	0.0362	<.0001	0.02419	<.0001
Pressure ulcer, hip	70704	0.09173	<.0001	0.09029	<.0001
Pressure ulcer, buttock	70705	0.00396	0.4043	0.0221	<.0001
Ulcer of lower limb NOS	70710	0.01138	0.0098	0.02116	<.0001
Ulcer other part of foot	70715	0.04066	<.0001	0.04168	<.0001
Ulcer oth part low limb	70719	0.03358	<.0001	0.02956	<.0001
Chronic skin ulcer NEC	7078	0.07843	<.0001	0.08132	<.0001
Syst lupus erythematosus	7100	0.24781	<.0001	0.23436	<.0001
Systemic sclerosis	7101	0.12899	<.0001	0.13113	<.0001
Pyogen arthritis-unspec	71100	0.03922	0.0151	0.07424	<.0001
Pyogen arthritis-l/leg	71106	0.11218	<.0001	0.09919	<.0001
Rheumatoid arthritis	7140	0.10921	<.0001	0.10251	<.0001
Inflamm polyarthrop NOS	7149	0.02641	0.1369	0.05225	0.0033
Sacroiliitis NEC	7202	0.16649	<.0001	0.17183	<.0001
Ac osteomyelitis-unspec	73000	-0.04005	0.0005	-0.01211	0.2959
Ac osteomyelitis-ankle	73007	-0.03799	<.0001	-0.02268	0.0005
Ac osteomyelitis NEC	73008	-0.01851	0.102	-0.01646	0.1459
Osteomyelitis NOS-hand	73024	0.05835	0.0001	0.06307	<.0001
Osteomyelitis NOS-ankle	73027	-0.03107	<.0001	-0.04842	<.0001
Path fx vertebrae	73313	0.1329	<.0001	0.1435	<.0001
Aseptic necrosis femur	73342	0.20291	<.0001	0.1894	<.0001
Asept necrosis bone NEC	73349	0.17431	<.0001	0.17243	<.0001
Coma	78001	0.02143	0.1083	0.03361	0.012
Fracture of pubis-closed	8082	0.06248	<.0001	0.04974	<.0001
Pelvic fracture NOS-clos	8088	-0.01048	0.4819	0.02635	0.0755
Fx femur intrcaps NEC-cl	82009	0.03652	0.0079	0.01917	0.1618
Fx neck of femur NOS-cl	8208	-0.02685	<.0001	-0.0007617	0.9099
Fx femur NOS-closed	82100	-0.05632	<.0001	-0.03439	0.0012
Amput below knee, unilat	8970	-0.10393	<.0001	-0.07656	<.0001
Amputat bk, unilat-compl	8971	-0.10582	<.0001	-0.07636	<.0001
Amput above knee, unilat	8972	-0.08573	<.0001	-0.06596	<.0001
Amputat leg, unilat NOS	8974	-0.077	<.0001	-0.05693	0.0017
React-indwell urin cath	99664	0.15093	<.0001	0.12326	<.0001
Compl heart transplant	99683	0.02305	0.3552	0.0336	0.1755
Asymp hiv infectn status	V08	0.37403	<.0001	0.35665	<.0001
Heart transplant status	V421	0.26702	<.0001	0.23506	<.0001
Liver transplant status	V427	0.16234	<.0001	0.13283	<.0001
Trnspl status-pancreas	V4283	0.14978	<.0001	0.10397	<.0001
Gastrostomy status	V441	0.02184	0.0173	0.01005	0.2728
Ileostomy status	V442	0.12312	<.0001	0.1086	<.0001
Colostomy status	V443	0.13378	<.0001	0.12704	<.0001
Urinostomy status NEC	V446	0.33981	<.0001	0.31177	<.0001
Respirator depend status	V4611	-0.02597	0.001	-0.02041	0.0095
Status amput othr toe(s)	V4972	0.031	<.0001	0.02001	<.0001
Status amput below knee	V4975	0.02473	<.0001	0.01286	0.0032
Status amput above knee	V4976	0.01774	0.0036	0.01293	0.034
Atten to gastrostomy	V551	-0.03053	0.0012	-0.01125	0.2309
Long-term use of insulin	V5867	0.12534	<.0001	0.10276	<.0001
BMI 40.0-44.9, adult	V8541	0.03116	<.0001	0.01971	0.0009

ICD-9 Description	ICD-9 Code	Baseline SHR		SDS/SES-adjusted SHR	
		Coefficient	P-value	Coefficient	P-value
Less than 6 months of Medicare eligible claims in the previous calendar year	—	0.73799	<.0001	0.5303	<.0001

Evaluating Adjustments for SDS/SES

Figure 1. Comparison of SHRs adjusted and not adjusted for race by facility percentage of black patients (deciles), 2013

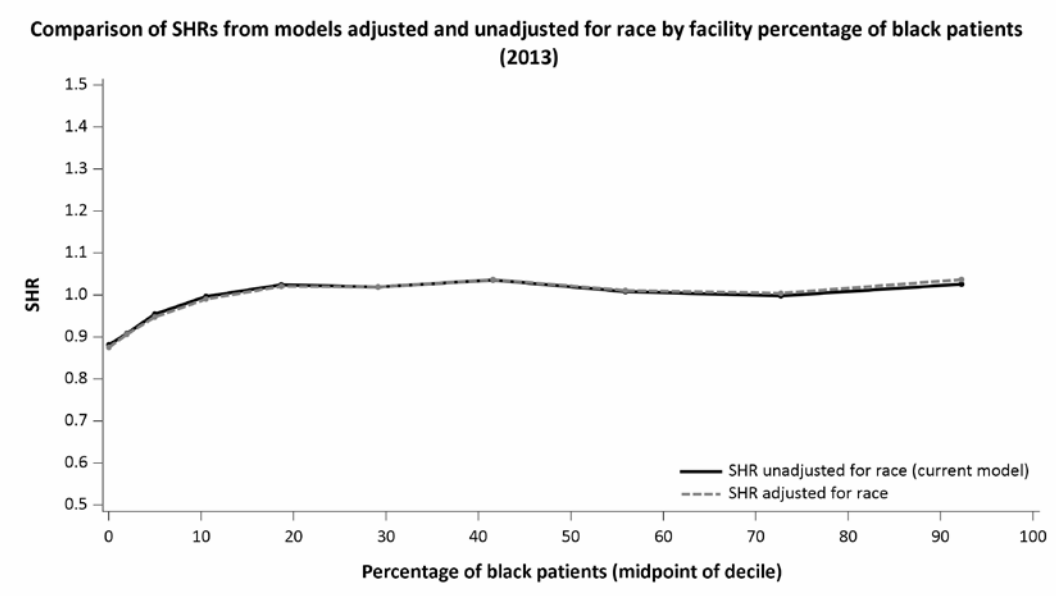


Figure 2. Comparison of SHRs adjusted and not adjusted for Hispanic ethnicity by facility percentage of Hispanic patients (deciles), 2013

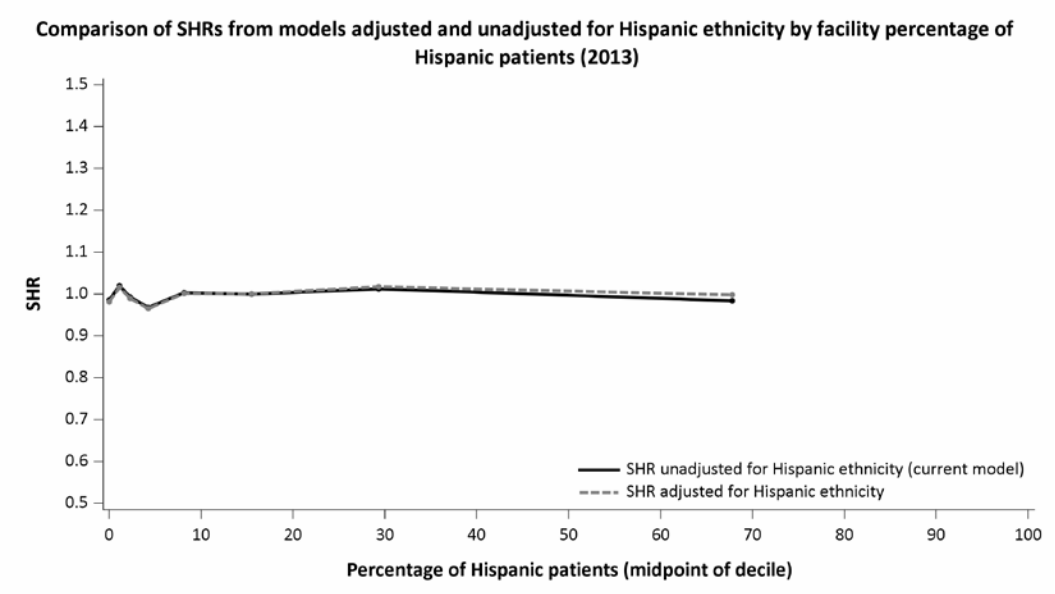
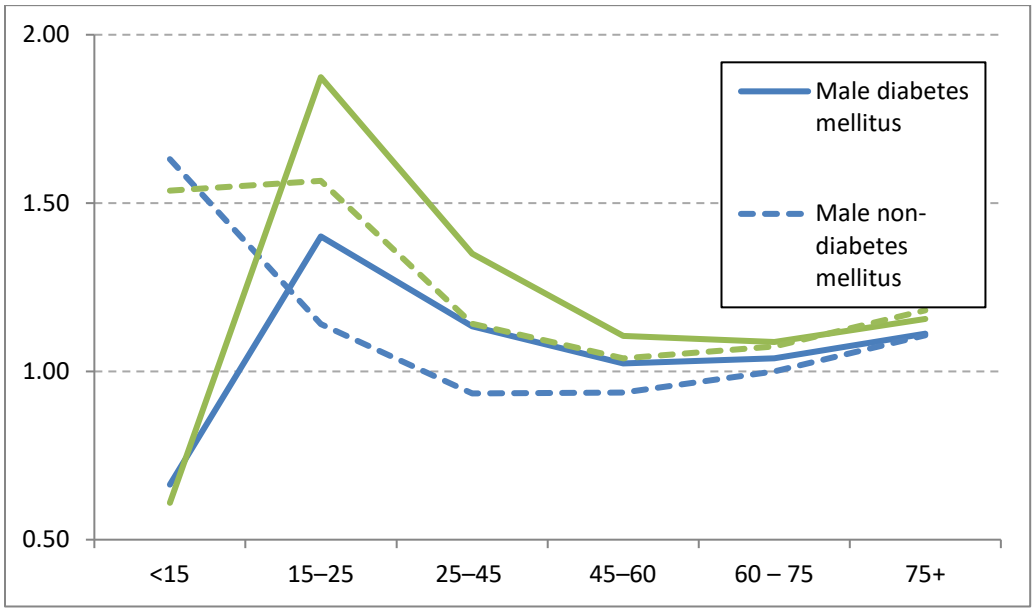


Figure 3. Relative effects of coefficients related to sex in the 2013 SHR model



Patient-level SDS: Compared with males, females were more likely to experience a hospital admission (OR=1.06; p<0.01).However the interaction of female sex and age demonstrated the highest odds were observed in the age 15 – 24, 25-44, and 45-59 age groups, with a decreasing gradient, and the 45-59 age group showing the most diminished impact. There was no significant difference in the oldest female-

age-specific group. These results suggest the possibility of an unidentified biologic effect or, alternatively, confounding by an unmeasured association for younger females. Hispanics were less likely to be admitted to the hospital (OR=0.92; p<0.01) than non- Hispanics. Compared with white patients, Asian/PI (OR=0.81, p<0.01), Native American (OR=0.97, p<0.01) and black (OR=0.94, p<0.01) patients were less likely to be admitted to the hospital. The results for ethnicity and race are consistent with prior studies within the dialysis setting.

Patient-level SES: Compared with Medicare-only patients, patients with both Medicare and Medicaid (OR=1.08; p<0.01) and patients with Medicare as secondary/Medicare HMO (OR=2.66, p<0.01) were more likely to be hospitalized. The result for dually eligible patients having higher odds of hospitalization is consistent with the hypothesis that this insurance category, on average, represents an at-risk group. Further examination is needed for the higher odds of hospitalization for patients with Medicare as secondary payer or HMO. It is possible that these patients represent a larger portion of incident ESRD patients, which have a known higher risk of complications in the first year of ESRD.

Patients who were employed prior to ESRD incidence were more likely to be admitted to the hospital (OR=1.05; p<0.01) than unemployed patients. Note that for employment categories, the "Other/Unknown" category also had higher odds of hospital admission. We note this represents diverse patient groups with regard to SES, such as students, homemakers and those who are retired. The higher odds of hospitalization may be associated with unmeasured risk characteristics of this diverse group but that will require further empirical examination based on data availability.

Area-level SES: Overall, measures of area-level deprivation had very low impact on the odds of hospitalization. Among statistically significant impacts were measures of low median family income (OR=0.998, p=0.0188), the percentage of families below the poverty level (OR=1.001, p=0.002), the percentage of individuals without a high school diploma (OR=1.002, p<0.01), and the area-level unemployment rate (OR=1.002, p<0.01). In general the magnitude of the effects of the individual indicators was very small. In addition to the very small coefficients, a few were not in the expected direction suggesting potential collinearity with other SES or SDS factors in the model.

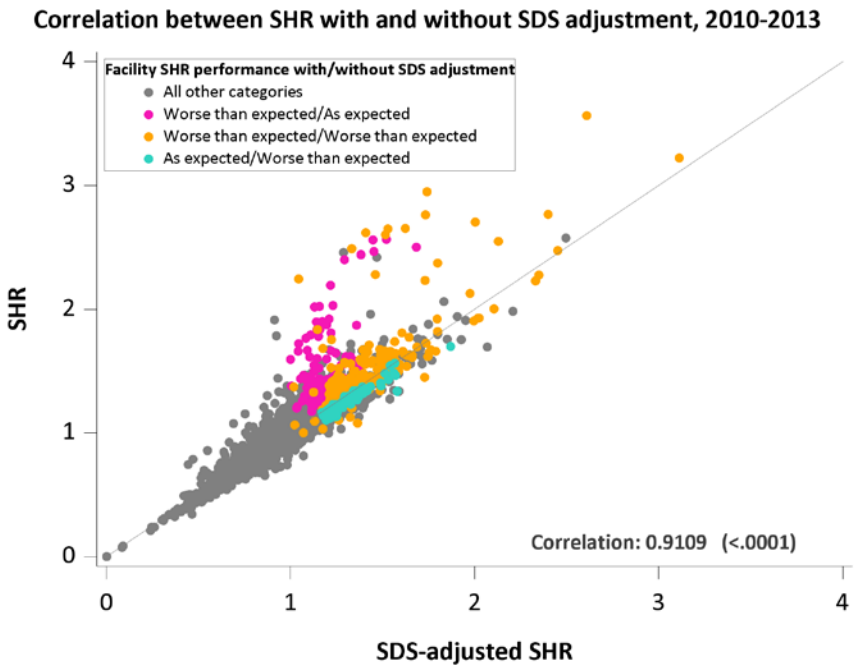


Table 4. Flagging rates, by model with and without all SDS/SES adjustors: 2010-2013

Baseline SHR	Model With SDS/SES			Total
	Better than Expected	As Expected	Worse than Expected	
Better than Expected	166	21	3	**190 (3.1%)**
As Expected	45	5546	81	**5672 (91.0%)**
Worse than Expected	5	123	244	**372 (6.0%)**
Total	**216 (3.5%)**	**5690 (91.3%)**	**328 (5.3%)**	—

After adjustment for SDS/SES, 278 facilities (4.5%) changed performance categories. 105 (1.7%) facilities were down-graded, and 173 (2.8%) were upgraded.

These analyses indicate that select patient-level variables for SDS/SES affect expected hospitalization rates, while area-level indicators had either minimal or no effect on expected hospital admissions. Furthermore, SHRs with and without adjustment for SDS/SES are highly correlated (0.9109) but adjustment for SDS/SES shifts facility performance only slightly. This suggests SDS/SES does not contribute much to the flagging profiles for facility performance.

In the final SHR model we continue to include sex (SDS factor) for risk adjustment. Our analysis of medical evidence and claims data is generally supportive of the current approach to sex adjustment in the SHR. It is consistent with the consensus opinion that adjustment for sex is appropriate, in that there is some evidence of physiological cause for higher hospitalization rates among females.

Table 3a above presents the manner in which the SHR adjusts for sex, given current judgment that physiology accounts for some, if not a substantial part, of observed differences in hospitalization by sex. The main adjustment reflects the observation that, adjusting for age and a set of comorbidities, females are more likely to be hospitalized. The interaction terms for age and sex in the model indicate that the effect of sex depends substantially on patient age. Females in the 15-45 age range face a greater risk of experiencing an admission, as compared to men of the same age with similar risk profiles. This does not appear to be a consequence of facility performance, however, because the disparity is not generally applicable to females, but only to a limited age group. It is therefore important to risk adjust for sex to ensure that women in facilities with larger numbers of women aged 15 to 45 are not inappropriately disadvantaged in terms of access to care.

Figure 3 shows the interaction of age and sex in the SHR model, for patients diagnosed with and without diabetes. The figure makes clear that for both male and female patients, independent of diagnoses of diabetes, hospitalization is strongly associated with young age. Further, the male-female difference is concentrated in the younger age categories. Beyond age 45, where the hospitalization rates are generally quite low, there is very little difference between males and females. The figure also demonstrates that high hospitalization rates for females reflects utilization by younger females, suggesting a physiologic effect rather than a systematic difference in care by sex.

Race and ethnicity and patient level SES factors are not included in the final risk adjusted model. While adjustment for these factors would account for different outcomes by race and ethnicity and SES factors and guard against barriers in access to care, adjustment would also introduce the potential unintended consequence of allowing access to lower quality of care. Additionally, race and Hispanic ethnicity were observed to indicate lower risk of hospitalization, including race, Hispanic ethnicity did not contribute more to the SHR compared to a model with most of the current set of adjustors; similarly for socioeconomic status (Figures 1-2 above). We are currently examining other measures of SES and SDS to assess impact on expected hospitalization and whether it would be appropriate to adjust for these factors.

Given the very small impact of area-level SES factors we decided not to include these as risk adjustments in the final model. While other studies have shown the association between these patient and area-level SDS/SES factors and hospitalization, further work is needed to demonstrate that differences based on these factors are not related to facility care, in order to prevent disparities in care. Patients in lower SES strata are typically in poorer health as they face greater resource limitation as a result of their limited access to primary care. Adjusting for SES would effectively further comprise the quality of care received as it would lower standards of care based on an assumption these patients will just generally always be sicker.

2019 Submission

The table below shows the parameter estimates for patient- and area-level SDS/SES variables based on a Cox model for hospital admissions that included these additional social risk factors along with the original covariates adjusted for in the baseline SHR.

Table 6. Comparing coefficients between sensitivity models with and without SDS/SES adjustors, 2015-2018: Model coefficients

Covariate	Baseline SHR			SDS/SES-adjusted SHR		
	Coefficient	P-value	Hazard Ratio	Coefficient	P-value^	Hazard Ratio^
Employment status						
Employed	--	--	--	Reference		
Unemployed	--	--	--	0.117	<.0001	1.124
Other	--	--	--	0.108	<.0001	1.114
Race						
White	--	--	--	Reference		
Black	--	--	--	-0.073	<.0001	0.930
Asian/Pacific Islander	--	--	--	-0.212	<.0001	0.809
Native American	--	--	--	-0.027	0.001	0.973
Other	--	--	--	-0.070	<.0001	0.932
Ethnicity						
Ethnicity: non-Hispanic	--	--	--	Reference		
Ethnicity: Hispanic	--	--	--	-0.107	<.0001	0.898
Ethnicity: Unknown	--	--	--	-0.108	<.0001	0.898
Medicare coverage						
Non-dual Eligible	--	--	--	Reference		
Dual Eligible	--	--	--	0.057	<.0001	1.059
ADI: National percentile ADI score	--	--	--	0.001	<.0001	1.001
Comorbidities at start of ESRD						
At least one of the comorbidities listed below	0.068	<.0001	1.071	0.063	<.0001	1.065
Atherosclerotic heart disease	0.049	<.0001	1.050	0.046	<.0001	1.048
Other cardiac disease	0.044	<.0001	1.045	0.041	<.0001	1.042
Diabetes	-0.028	<.0001	0.972	-0.027	<.0001	0.973
Congestive heart failure	0.040	<.0001	1.041	0.037	<.0001	1.038
Inability to ambulate	0.035	<.0001	1.036	0.027	<.0001	1.027
Chronic obstructive pulmonary disease	0.070	<.0001	1.072	0.062	<.0001	1.064
Inability to transfer	0.018	0.001	1.018	0.020	3E-04	1.020
Malignant neoplasm, cancer	0.044	<.0001	1.045	0.042	<.0001	1.043

Covariate	Baseline SHR			SDS/SES-adjusted SHR		
	Coefficient	P-value	Hazard Ratio	Coefficient	P-value^	Hazard Ratio^
Peripheral vascular disease	0.042	<.0001	1.043	0.037	<.0001	1.038
Cerebrovascular disease, CVA, TIA	0.015	<.0001	1.015	0.011	<.0001	1.011
Tobacco use (current smoker)	0.127	<.0001	1.136	0.118	<.0001	1.126
Alcohol dependence	0.017	0.0058	1.017	0.011	0.079	1.011
Drug dependence	0.208	<.0001	1.231	0.188	<.0001	1.207
No Medical Evidence (CMS-2728) Form	0.029	0.002	1.030	0.023	0.179	1.023
Cause of ESRD						
Diabetes	0.726	--	--	0.747	--	--
Missing	0.116	<.0001	1.123	0.178	<.0001	1.195
Sex: Female	0.412	--	--	0.423	--	--
Age						
Age (continuous)	-0.020	--	--	-0.017	--	--
Age squared	0.00017	--	--	0.00015	--	--
BMI						
BMI < 18.5	0.119	<.0001	1.126	0.118	<.0001	1.125
18.5 ≤ BMI < 25	0.077	<.0001	1.080	0.081	<.0001	1.084
25≤ BMI < 30	0.043	<.0001	1.044	0.046	<.0001	1.047
BMI≥30	Reference			Reference		
Medicare coverage						
Proportion of months with Medicare Advantage	-0.165	<.0001	0.848	-0.165	<.0001	0.848
Calendar year						
2015	Reference			Reference		
2016	-0.027	<.0001	0.973	-0.027	<.0001	0.974
2017	-0.068	<.0001	0.935	-0.066	<.0001	0.936
2018	-0.057	<.0001	0.944	-0.056	<.0001	0.946
Nursing home during the prior 365 days						
No nursing home care (0 days)	Reference			Reference		
Short-term nursing home care (<90 days)	0.227	<.0001	1.255	0.221	<.0001	1.248
Long-term nursing home care (>=90 days)	0.109	<.0001	1.116	0.091	<.0001	1.096
Interaction: Diabetes as Cause of ESRD and female sex	-0.017	<.0001	0.983	-0.020	<.0001	0.981
Interaction: Diabetes as cause of ESRD and						
Age (continuous)	-0.019	<.0001	0.981	-0.020	<.0001	0.980
Age squared	0.00012	<.0001	1.000	0.00013	<.0001	1.000
Interaction: female sex and						
Age (continuous)	-0.008	<.0001	0.992	-0.009	<.0001	0.991
Age squared	0.00004	<.0001	1.000	0.00005	<.0001	1.000

Covariate	Baseline SHR			SDS/SES-adjusted SHR		
	Coefficient	P-value	Hazard Ratio	Coefficient	P-value^	Hazard Ratio^
Prevalent Comorbidities (condition groups)						
Candidal esophagitis	0.184	<.0001	1.202	0.185	<.0001	1.204
Sarcoidosis	0.106	<.0001	1.112	0.108	<.0001	1.114
Cancer of Liver	0.278	<.0001	1.320	0.283	<.0001	1.328
Cancer of Lung	0.251	<.0001	1.285	0.252	<.0001	1.287
Cancer of Prostate	0.088	<.0001	1.092	0.097	<.0001	1.102
Cancer of Bladder	0.220	<.0001	1.246	0.215	<.0001	1.240
Cancer of Kidney	0.086	<.0001	1.090	0.087	<.0001	1.091
Cancer of Bone	0.292	<.0001	1.339	0.291	<.0001	1.338
Other Neoplasm	0.143	<.0001	1.153	0.140	<.0001	1.150
Non-Hodgkins Lymphoma	0.176	<.0001	1.193	0.177	<.0001	1.194
Multiple Myeloma	0.234	<.0001	1.264	0.240	<.0001	1.271
Chronic lymphoid leukemia	0.197	<.0001	1.217	0.194	<.0001	1.214
Myelodysplastic Syndrome	0.192	<.0001	1.212	0.194	<.0001	1.214
Essential Thrombocytopenia	0.122	<.0001	1.130	0.123	<.0001	1.131
Diabetes without complications	0.163	<.0001	1.177	0.165	<.0001	1.179
Diabetes with complications	0.220	<.0001	1.246	0.221	<.0001	1.247
Glucocorticoid deficiency	0.151	<.0001	1.163	0.152	<.0001	1.164
Malnutrition / Cachexia	0.104	<.0001	1.110	0.106	<.0001	1.112
Disorders of urea cycle metabolism	0.143	<.0001	1.154	0.144	<.0001	1.155
Other amyloidosis	0.128	<.0001	1.137	0.125	<.0001	1.133
Other specified disorders of metabolism	0.111	<.0001	1.117	0.109	<.0001	1.115
Morbid Obesity	0.012	<.0001	1.012	0.007	0.003	1.007
Sickle-cell Anemia	0.654	<.0001	1.923	0.654	<.0001	1.923
Pancytopenia	0.182	<.0001	1.200	0.179	<.0001	1.196
Neutropenia	0.101	<.0001	1.107	0.101	<.0001	1.106
Primary hypercoagulable state	0.119	<.0001	1.126	0.114	<.0001	1.121
Dementia	0.043	<.0001	1.044	0.046	<.0001	1.047
Substance Related Disorders	0.274	<.0001	1.315	0.267	<.0001	1.306
Miscellaneous Mental Health	0.070	0.0015	1.072	0.075	0.0006	1.078
Opioid Dependance	0.309	<.0001	1.362	0.296	<.0001	1.345
Schizophrenia	0.142	<.0001	1.153	0.132	<.0001	1.141
Cerebral degeneration, unspecified	0.044	0.0048	1.045	0.045	0.004	1.046
Peripheral autonomic neuropathy in disorders classified elsewhere	0.147	<.0001	1.158	0.143	<.0001	1.154
Unspecified hereditary and idiopathic peripheral neuropathy	0.143	<.0001	1.154	0.141	<.0001	1.151

Covariate	Baseline SHR			SDS/SES-adjusted SHR		
	Coefficient	P-value	Hazard Ratio	Coefficient	P-value^	Hazard Ratio^
Epilepsy	0.199	<.0001	1.220	0.193	<.0001	1.212
Bipolar Disorder	0.231	<.0001	1.260	0.211	<.0001	1.235
Major depressive affective disorder	0.208	<.0001	1.231	0.200	<.0001	1.222
Mood Disorders	0.159	<.0001	1.173	0.154	<.0001	1.167
Alcohol Related Disorders	0.150	<.0001	1.162	0.145	<.0001	1.157
Coma	0.001	0.865	1.001	0.004	0.606	1.004
Cerebral edema	0.018	0.1571	1.019	0.024	0.062	1.025
Critical illness myopathy	-0.167	<.0001	0.846	-0.163	<.0001	0.850
hypertensive heart disease with heart failure	0.087	<.0001	1.091	0.087	<.0001	1.091
Myocardial Infarction	0.131	<.0001	1.140	0.132	<.0001	1.141
Coronary Atherosclerosis	0.180	<.0001	1.197	0.181	<.0001	1.198
pulmonary embolism and infarction	0.132	<.0001	1.141	0.134	<.0001	1.143
Primary pulmonary hypertension	0.092	<.0001	1.096	0.095	<.0001	1.099
Pulmonary Heart Disease	0.122	<.0001	1.130	0.125	<.0001	1.133
Cardiomyopathy	0.138	<.0001	1.148	0.140	<.0001	1.150
Atrioventricular block, complete	-0.018	0.0223	0.982	-0.018	0.021	0.982
Paroxysmal Tachycardia	0.084	<.0001	1.088	0.085	<.0001	1.089
Atrial fibrillation	0.135	<.0001	1.145	0.133	<.0001	1.143
Atrial flutter	0.039	<.0001	1.040	0.040	<.0001	1.041
Sinoatrial node dysfunction	0.019	<.0001	1.020	0.022	<.0001	1.022
Acute Cerebrovascular Disease	0.048	<.0001	1.049	0.052	<.0001	1.053
Peripheral and Visceral Atherosclerosis	0.130	<.0001	1.139	0.129	<.0001	1.138
Venous Thromboembolism	0.145	<.0001	1.156	0.146	<.0001	1.157
Esophageal varices	0.219	<.0001	1.245	0.224	<.0001	1.251
Chronic Obstructive Pulmonary Disease	0.198	<.0001	1.219	0.189	<.0001	1.209
Asthma	0.049	<.0001	1.050	0.047	<.0001	1.048
Aspiration Pneumonitis	0.040	<.0001	1.041	0.040	<.0001	1.041
Other Lower Respiratory Diseases	0.130	<.0001	1.139	0.134	<.0001	1.143
Respiratory Failure	0.139	<.0001	1.149	0.139	<.0001	1.149
Enteritis and Ulcerative Colitis	0.133	<.0001	1.143	0.127	<.0001	1.135
Ileus and Intestinal Obstruction	0.099	<.0001	1.104	0.099	<.0001	1.104
Cirrhosis of Liver	0.207	<.0001	1.230	0.204	<.0001	1.226
Other Liver Disease	0.202	<.0001	1.223	0.201	<.0001	1.223
Pancreatitis	0.337	<.0001	1.401	0.333	<.0001	1.395
Chronic Skin Ulcer	0.086	<.0001	1.089	0.084	<.0001	1.088

Covariate	Baseline SHR			SDS/SES-adjusted SHR		
	Coefficient	P-value	Hazard Ratio	Coefficient	P-value^	Hazard Ratio^
Systemic lupus erythematosus and connective tissue disorders	0.240	<.0001	1.271	0.243	<.0001	1.275
Infective arthritis and osteomyelitis	-0.031	<.0001	0.969	-0.031	<.0001	0.969
Rheumatoid Arthritis	0.135	<.0001	1.144	0.133	<.0001	1.142
Pathologic Fracture	0.131	<.0001	1.140	0.134	<.0001	1.143
Aseptic Necrosis	0.154	<.0001	1.166	0.152	<.0001	1.164
Hip and Femur Fracture	-0.053	<.0001	0.948	-0.054	<.0001	0.947
Gangrene	0.018	<.0001	1.019	0.024	<.0001	1.024
Infection due to urinary catheter	0.101	<.0001	1.106	0.097	<.0001	1.102
HIV	0.339	<.0001	1.404	0.334	<.0001	1.397
Solid Organ Transplant	0.140	<.0001	1.150	0.131	<.0001	1.140
Gastrostomy status	0.064	<.0001	1.066	0.068	<.0001	1.070
Ileostomy / Colostomy Status	0.168	<.0001	1.183	0.162	<.0001	1.176
Other artificial opening of urinary tract status	0.261	<.0001	1.298	0.251	<.0001	1.285
Dependence on respirator, status	-0.103	<.0001	0.902	-0.102	<.0001	0.903
Other toe(s) amputation status	0.072	<.0001	1.075	0.069	<.0001	1.072
Below knee amputation status	-0.009	0.025	0.991	-0.012	0.002	0.988
Above knee amputation status	0.017	0.0031	1.017	0.016	0.006	1.016
Long-term (current) use of insulin	0.102	<.0001	1.108	0.102	<.0001	1.107
Cancer of Rectum	0.113	<.0001	1.120	0.113	<.0001	1.119
Inflammatory polyarthropathy	0.261	<.0001	1.299	0.265	<.0001	1.303
Sacroiliitis	0.182	<.0001	1.200	0.187	<.0001	1.205
Less than 6 months of Medicare eligible claims in the previous calendar year	0.478	<.0001	1.612	0.494	<.0001	1.639

^Interpretation of covariate main effects that are also included in interaction terms is not straightforward. Because of this coefficient p-values and HRs are not reported for the main effect covariates. Interaction terms can be interpreted directly. For example, the interaction between female sex and age means that the effect of female depends on age.

Figure 1. Comparison of SHRs adjusted and not adjusted for race by facility percentage of black patients (deciles), 2018

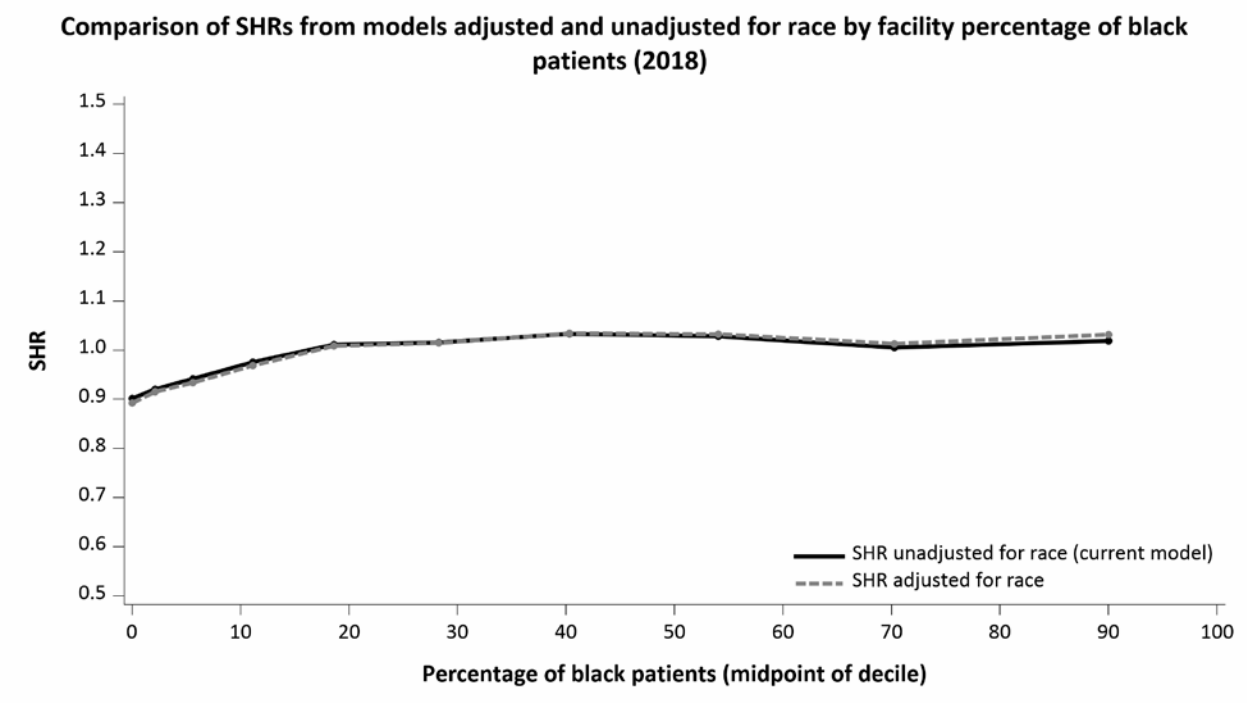


Figure 2. Comparison of SHRs adjusted and not adjusted for Hispanic ethnicity by facility percentage of Hispanic patients (deciles) 2018

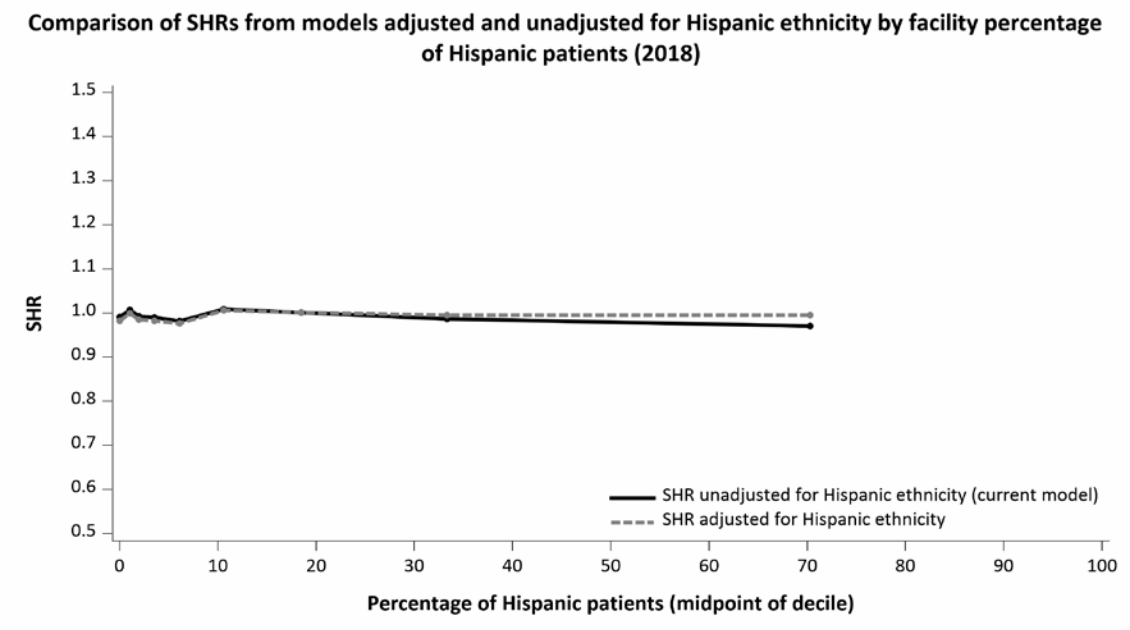
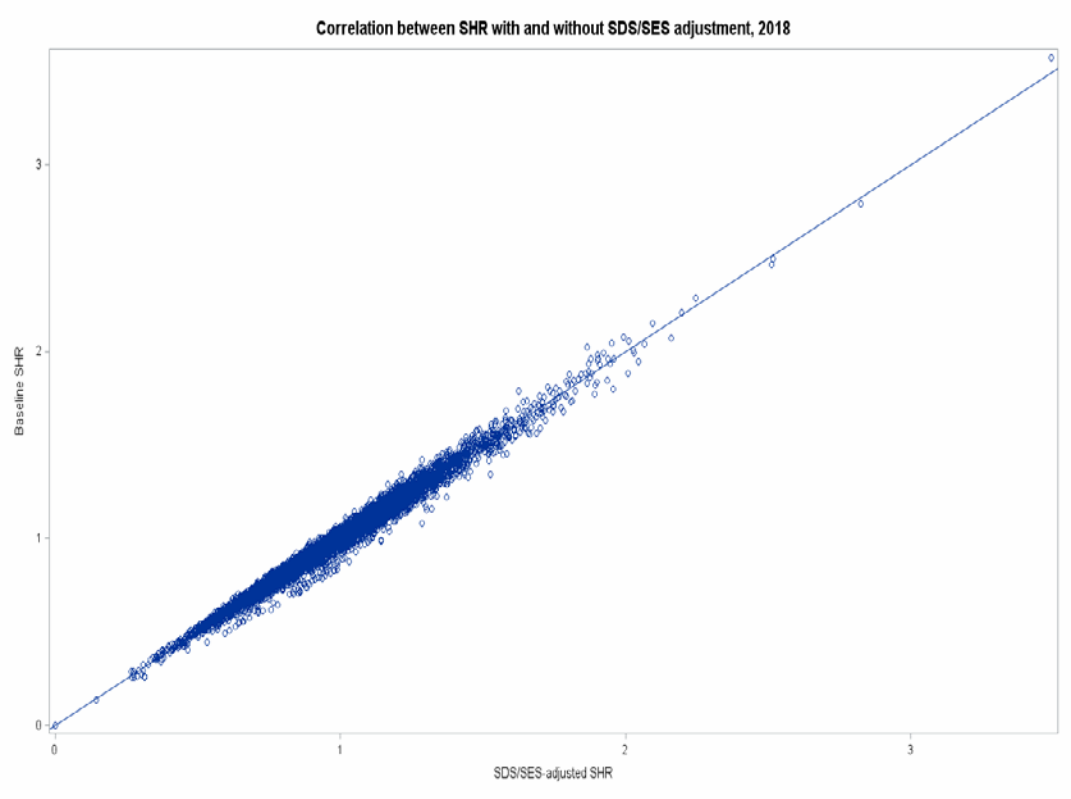


Figure 3: Correlation between SHR with and without SDS/SES adjustment, 2018



ρ = 0.992(P<0.0001)

Table 7: Flagging rates, by model with and without SDS/SES adjustors: 2018

Baseline SHR	**Model With SDS/SES**			**Total**
	Better than Expected	As Expected	Worse than Expected	
Better than Expected	54	23	0	**77 (1.09%)**
As Expected	16	6659	29	**6704 (95.2%)**
Worse than Expected	0	20	241	**261 (3.71%)**
Total	**70 (0.99%)**	**6702 (95.17%)**	**270 (3.83%)**	—

After adjustment for SDS/SES, 88 facilities (1.2%) changed performance categories. 52 (0.7%) facilities were down-graded, and 36 (0.5%) were upgraded.

Patient race, Hispanic ethnicity, and female sex were associated with lower hospitalization. The impact of sex however is conditional on the respective relationships with other risk factors captured in the

interaction terms in the SHR. Among SES factors unemployment and dual eligible status were associated with hospitalization (higher risk) while the impact of area level SES deprivation was no different than the national average. In SHR adjustment for SDS/SSES shifts facility performance, however more facilities were downgraded in the model with SDS/SES adjustment. SHR with and without adjustment for patient SDS/SES and area SES were highly correlated.

Race, Hispanic ethnicity, and SES factors are not included in the final risk adjusted model for SHR. While other studies have shown the association between these patient SDS/SES and area-level SES factors and hospitalization, further work is needed to demonstrate that differences based on these factors are not related to facility care, in order to prevent disparities in care. In the absence of definitive evidence demonstrating risk adjustment for these social factors does not result in differential access to care, the most appropriate decision is not to risk adjust for these SDS/SES factors. The primary goal should be to implement quality measures that result in the highest quality of patient care and equitable access for all patients to that care.

In the final SHR model we continue to include sex (SDS factor) for risk adjustment. This approach is consistent with the consensus opinion that adjustment for sex is appropriate based on biologic differences (e.g. genetic, hormonal, metabolic) that may account for higher acute care use (hospital utilization), suggesting a physiologic effect rather than a systematic difference or disparity in care by sex.

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

Provide the statistical results from testing the approach to controlling for differences in patient characteristics (case mix) below.
If stratified, skip to 2b3.9

2016 Submission
Two-way interactions were examined and selected for the final model based on both the magnitude and statistical significance of the estimates.

2019 Submission
Risk factors were selected for the final model based on the magnitude of the coefficients, evaluation of their statistical significance, and the model C-statistic. The C-statistic measures the discriminative power of the regression model with considered risk factors. Two-way interactions were examined and selected for the final model based on both the magnitude and statistical significance of the estimates.

2b3.6. Statistical Risk Model Discrimination Statistics (*e.g., c-statistic, R-squared*)**:**
2016 Submission
The C-statistic for a recurrent event model measures the concordance between the observed rate of recurrent events and the model-based rate. The estimate of the c-statistic for the SHR is 0.65.

2019 Submission

The estimate of the C-statistic for the SHR is 0.621.

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

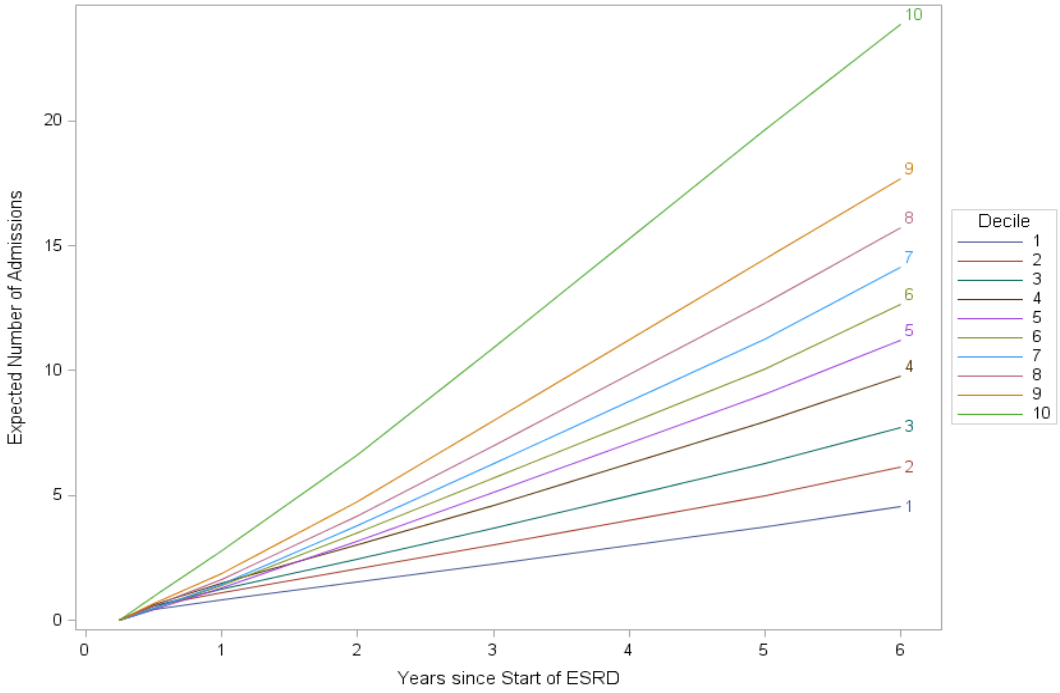
N/A

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

2016 Submission

Decile plots showing piecewise linear estimates of the cumulative rates by years since start of ESRD are plotted in Figure 4.

Figure 4. Decile Plot for SHR Admissions (2013 data).



Martingale residual plots were also examined (Figures 5-7).

Figure 5. Martingale Residuals by Age of Patient with LOESS Curve (2013 data).

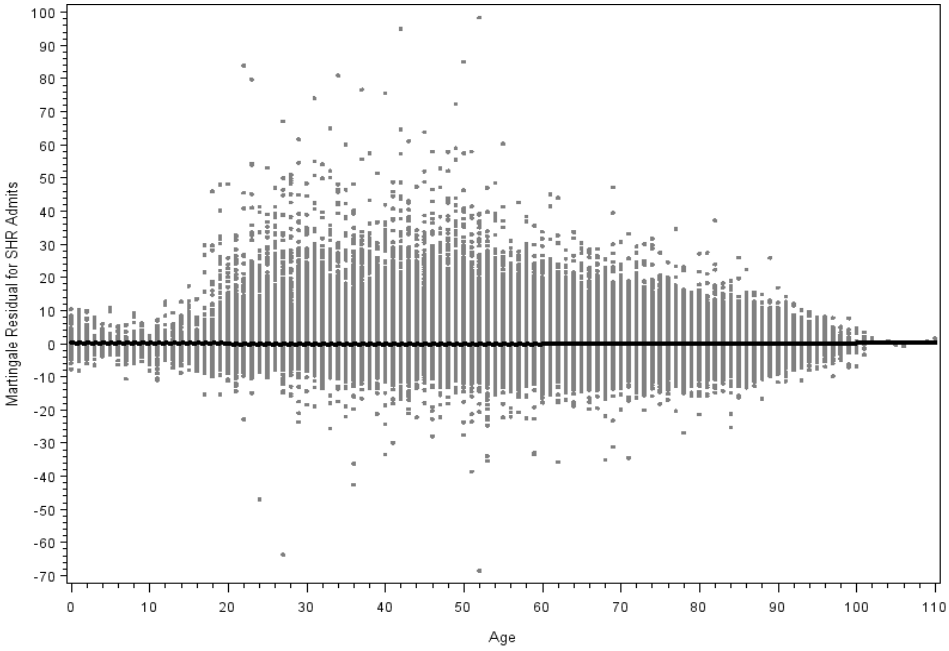


Figure 6. Martingale Residuals by BMI of Patient with LOESS Curve (2013 data).

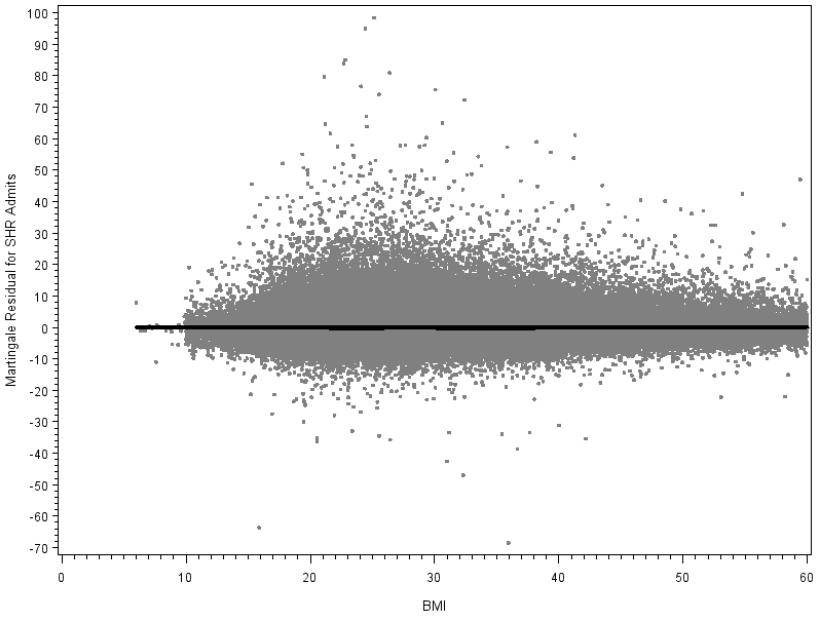
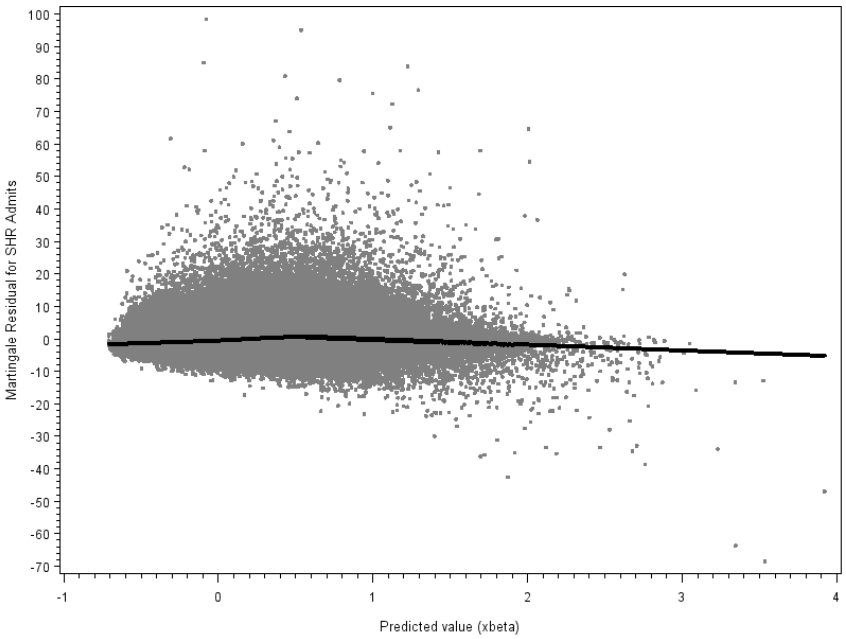


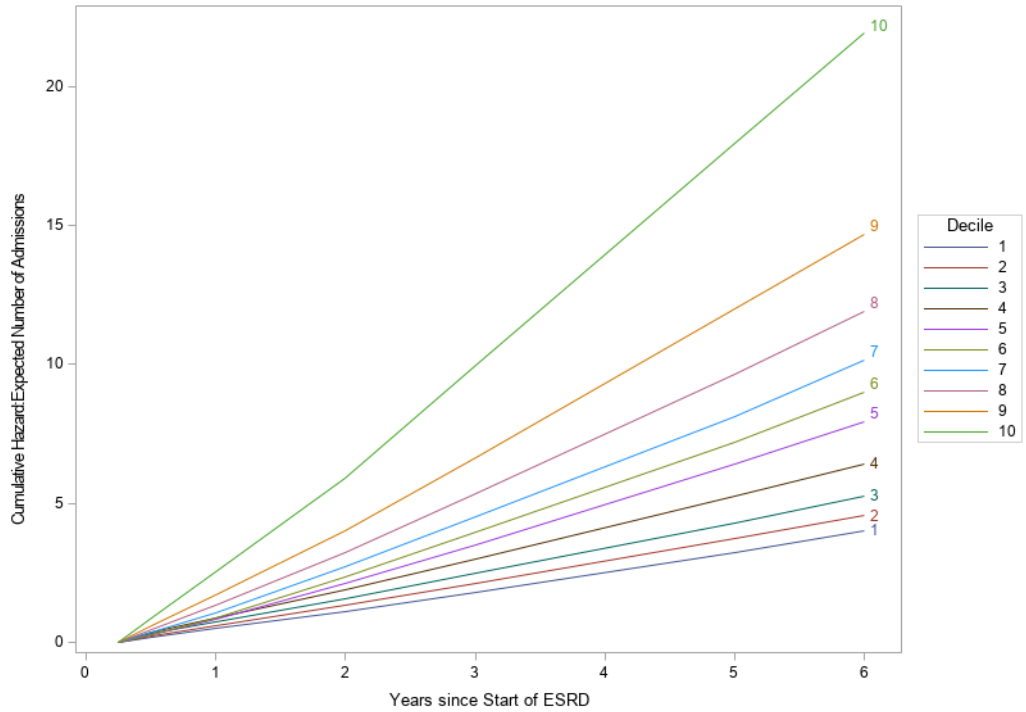
Figure 7. Martingale Residuals by Predicted Value of Patient with LOESS Curve (2013 data).



2019 Submission

Decile plots showing piecewise linear estimates of the cumulative rates by years since start of ESRD are plotted in Figure 4.

Figure 4. Decile Plot for SHR Admissions (2018 data).



Martingale residual plots were also examined (Figures 5-7).

Figure 5. Martingale Residuals by Age of Patient with LOESS Curve (2018 data).

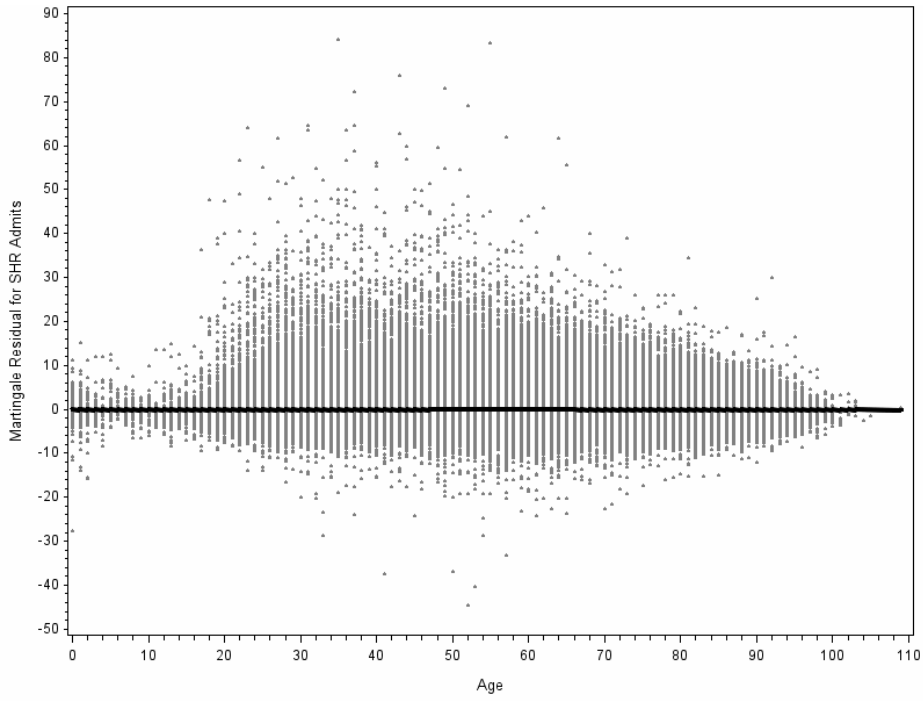


Figure 6. Martingale Residuals by BMI of Patient with LOESS Curve (2018 data).

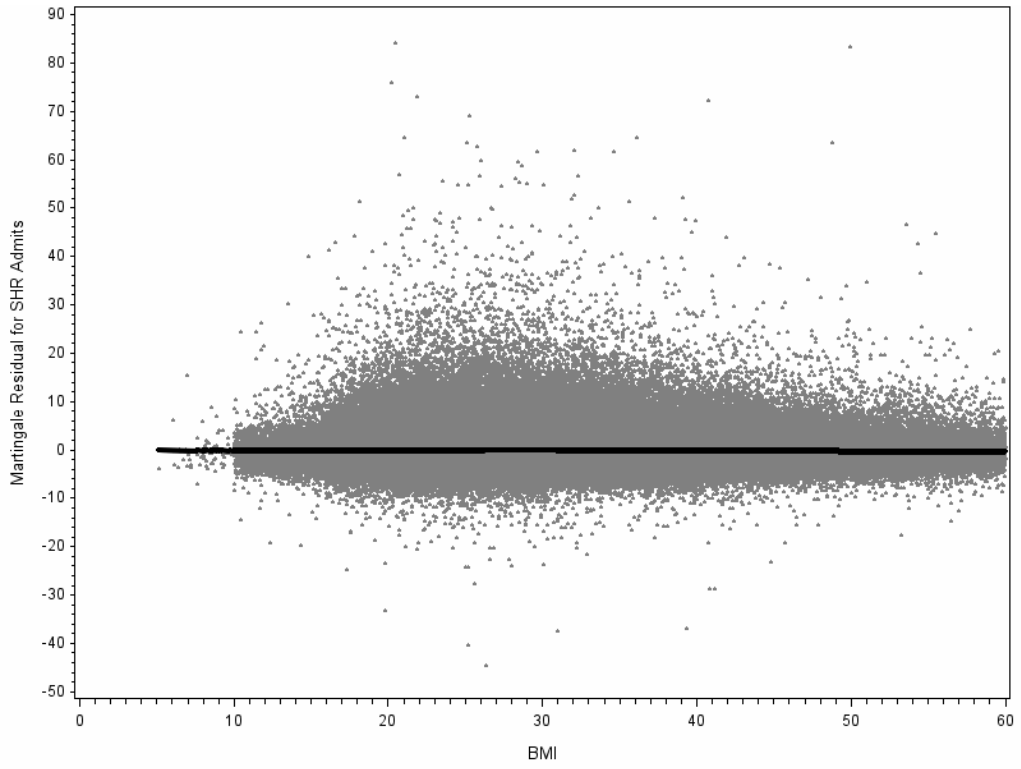
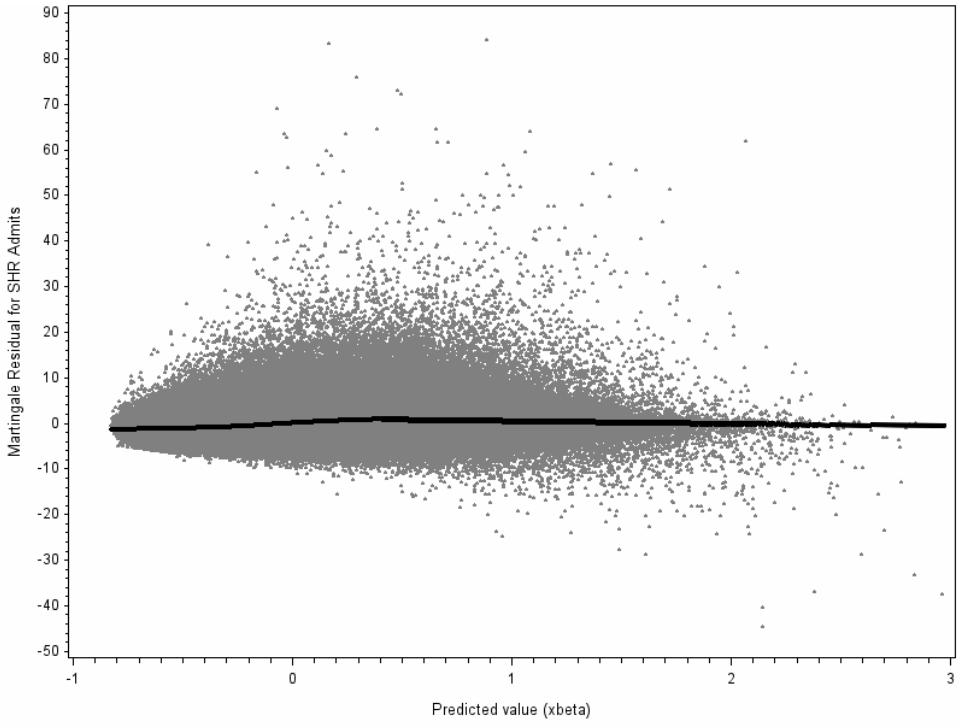


Figure 7. Martingale Residuals by Predicted Value of Patient with LOESS Curve (2015-2018 data).



2b3.9. Results of Risk Stratification Analysis:
N/A

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

2016 Submission

The decile plot shows that the risk factors in the model are discriminating well between patients. There is good separation among all 10 groups, and the ordering is as predicted by the model (patients predicted to be at lower risk have lower hospitalization rates). The absolute differences between the groups is also large, with patients predicted to have the highest hospitalization rates (line 10) having 3 times higher hospitalization rates than those predicted to have the lowest rates (line 1).

The Martingale residual plots also did not indicate problems with the model fit. There was no pattern in the residuals that suggested lack of fit in any of the variables considered. In the LOESS plots attached, the LOESS curve for the mean of the residuals is flat indicating that there is no problem with the fit for each of the variables considered. The adjustment variables are highly predictive of the hospital admissions, and model extensions to examine interactions suggest a good overall fit.

2019 Submission

Decile plots shows piecewise linear estimates of the cumulative rates by years since the start of ESRD. The plot demonstrates that the risk factors in the model are discriminating well between patients. There is good separation among all 10 groups and the ordering is as predicted by the model (patients predicted to be at lower risk have lower hospitalization rates). The absolute differences between the groups is also large with patients predicted to have the highest hospitalization rates (line 10) having almost 4 times higher hospitalization rates than those predicted to have the lowest rates (line 1).

The Martingale residual plots also did not indicate problems with the model fit. There was no pattern in the residuals that suggested lack of fit in any of the variables considered. In the LOESS plots attached, the LOESS curve for the mean of the residuals is flat indicating that there is no problem with the fit for each of the variables considered. The adjustment variables are highly predictive of the hospital admissions, and model extensions to examine interactions suggest a good overall fit.

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

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

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

2016 Submission

To adjust for over-dispersion of the data, we compute the p-value for our estimates using the empirical null distribution, a robust approach that takes account of the natural random variation among facilities that is not accounted for in the model (Efron, 2004; Kalbfleisch and Wolfe, 2013). Our algorithm consists of the following concrete steps. First, we fit an over-dispersed Poisson model (e.g., SAS PROC GENMOD with link=log, dist=poisson and scale=dscale) for the number of hospital admissions

$$\log(E[\mathbf{n}_{ik}]) = \log(\mathbf{E}_{ik}) + \boldsymbol{\theta}_k,$$

where $\mathbf{n}_{ik}$ is the observed number of events for patient *i* in facility *k*, $\mathbf{E}_{ik}$ is the expected number of events for patient *i* in facility *k* and $\boldsymbol{\theta}_k$ is the facility-specific intercept. Here, i ranges over the number of patients N_k who are treated in the *k*th facility. The natural log of the SHR for the *k*th facility is then given by the corresponding estimate of $\boldsymbol{\theta}_k$. The standard error of $\boldsymbol{\theta}_k$ is obtained from the robust estimate of variance arising from the overdispersed Poisson model.

Second, we obtain a z-score for each facility by dividing the natural log of its SHR by the standard error from the generalized linear model described above. These z-scores are then grouped into quartiles based on the number of patient years at risk for Medicare patients in each facility. Finally, using robust estimates of location and scale based on the normal curve fitted to the center of the z-scores for the

SHR, we derive the mean and variance of a normal empirical null distribution for each quartile. This empirical null distribution is then used to calculate the p-value for a facility's SHR.

2019 Submission
The methodology described above was applied again to the testing for this submission

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

2016 Submission

Table 5. Number and percentage of facilities by classification of SHR, 2013. Categories stratified by facility size.

Number of patients	Better than expected	As expected	Worse than expected
< 51	0.26% (15)	31.86% (1,866)	1.47% (86)
51 - 87	0.39% (23)	31.71% (1,857)	1.79% (105)
> 87	0.43% (25)	30.46% (1,784)	1.64% (96)

2019 Submission

Table 8. Number and percentage of facilities by classification of SHR

Better than Expected	As Expected	Worse than Expected
77 (1.09%)	6,704 (95.20%)	261 (3.71%)

2b4.3. What is your interpretation of the results in terms of demonstrating the ability to identify statistically significant and/or clinically/practically meaningful differences in performance across measured entities? (i*.e., what do the results mean in terms of statistical and meaningful differences?*)

2016 Submission
Without empirical null methods, a large number of facilities will be flagged, including many larger facilities with a relatively small difference between the rates of hospitalization. In contrast, the methods based on the empirical null make appropriate adjustments for overdispersion. Using this method, facilities are flagged if they have outcomes that are extreme when compared to the variation in outcomes for other facilities of a similar size. Overall, most facilities are flagged as expected (94.03%), while approximately 1% are better than expected, and approximately 5% are flagged as worse than expected.

2019 Submission

Without empirical null methods, a large number of facilities will be flagged, including many larger facilities with a relatively small difference between the rates of hospitalization. In contrast, the methods based on the empirical null make appropriate adjustments for overdispersion. Using this method, facilities are flagged if they have outcomes that are extreme when compared to the variation in outcomes for other facilities of a similar size. Overall, most facilities are flagged as expected (95.20%), while approximately 1% are better than expected, and approximately 4% are flagged as worse than expected.

2b5. COMPARABILITY OF PERFORMANCE SCORES WHEN MORE THAN ONE SET OF SPECIFICATIONS
If only one set of specifications, this section can be skipped.

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

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

N/A

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

N/A

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

N/A

2b6. MISSING DATA ANALYSIS AND MINIMIZING BIAS

2b6.1. Describe the method of testing conducted to identify the extent and distribution of missing data (or nonresponse) and demonstrate that performance results are not biased due to systematic missing data (or differences between responders and nonresponders) and how the specified handling of missing data minimizes bias (*describe the steps—do not just name a method; what statistical analysis*

was used)

The SHR measure is dependent on Medicare claims and other CMS administrative data for several important components of measure calculation, including ascertainment of prevalent comorbidities for risk adjustment and to determine patient time at risk. For these reasons, SHR is a measure limited to Medicare patients.

For several Medicare-only measures developed by UM-KECC, the presence of active Medicare coverage has been defined using a combination of criteria including a defined minimum dollar amount of claims for dialysis services and/or presence of a Medicare inpatient claim during an eligibility period. With the recent increase in Medicare Advantage (MA) coverage for Medicare chronic dialysis patients, and the known systemic issue of unavailable outpatient claims data for MA patients, these criteria have the potential to introduce significant bias into measure calculations that could affect results for dialysis facilities with either very low or high MA patient populations, particularly for SHR as the outcome being measured is inpatient hospitalization.

As part of the comprehensive measure review process, we assessed the extent of MA coverage for ESRD dialysis patients and the effect of our historical definition of "active Medicare" status on the measure result. Medicare Advantage patient status was defined using Medicare Enrollment Database (EDB) criteria. Primary Medicare Fee for Service (FFS) coverage was identified using CMS administrative data, and active Medicare status utilized the combination of a minimum dollar amount of dialysis claims and/or inpatient Medicare hospitalization claims briefly described above. We confirmed the presence of usable ICD diagnosis codes from MA inpatient claims and the nearly complete absence of outpatient Medicare claims data for patients identified as MA in the CMS data used for our measure calculation.

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

Summary findings:

- The percentage of patients with MA coverage receiving chronic dialysis in US dialysis facilities has approximately doubled in the last decade and is approaching 20% based on 2017 data.
- When applied to MA patients, the historical definition of active Medicare coverage (described earlier) creates systematic bias in the SHR measure calculation through exclusion of MA patient time at risk in facilities unless the MA patient had one or more hospitalizations in the observation period. MA patients included because of hospitalization are very likely not representative of MA patients as a whole, instead reflecting a sicker subset. This has the potential to result in very high SHRs in facilities with a higher proportion of MA patients. Calculating SMR using an alternative definition of time at risk for MA patients (using the Medicare EDB rather than inpatient or outpatient claims-based utilization), results in little or no change in our ability to identify hospital discharges from Medicare claims, as Medicare Advantage hospitalizations are available in the inpatient Medicare claims.
- We confirmed the presence of usable ICD diagnosis codes from MA inpatient claims and the nearly complete absence of outpatient Medicare claims data for patients identified as MA in the CMS data used for our measure calculation

Additional analyses (Table 9) demonstrate a variable distribution of Medicare Advantage ESRD dialysis patient proportion following geographic boundaries. For example, the percentage of MA ESRD patient time at risk relative to total Medicare ESRD patient time at risk varies from a low of 2.2% in Wyoming to a high of 44.2% in Puerto Rico.

Table 9. Average of Dialysis Facilities' Percent of MA Patients[1] by State, 2018.

State	N	Mean (SD)
PR	44	44.2 (14.5)
RI	16	33.6 (18.5)
HI	31	27.8 (11.2)
OH	323	26.8 (11.4)
PA	307	25 (14.5)
AZ	121	24.6 (12.5)
CA	658	23.9 (16.6)
MN	119	23.5 (10.6)
OR	71	22.9 (15.3)
MI	211	22.4 (10.1)
TN	185	21 (8.9)
AL	176	19.8 (10.5)
FL	456	19.6 (10.3)
CO	125	18.7 (8.9)
WI	80	18.7 (11)
TX	675	18.6 (10.9)
NY	353	17.2 (7.6)
GA	296	17.2 (8.8)
NV	49	16.9 (9.7)
WV	45	16.6 (8.2)
KY	120	16.2 (6.7)
MO	165	15.2 (9.1)
NC	220	14.9 (8.6)
SC	150	14.4 (6.6)
IN	166	14.2 (8.1)
LA	175	14 (10)
NM	54	13.9 (12.2)
IL	317	13.2 (9.5)
MA	84	13.1 (11.8)
NJ	48	12.7 (4.9)
CT	179	12.7 (6.3)
VI	4	12.5 (25)
ID	43	12.1 (8.5)
UT	28	12.1 (8.9)
ME	17	11.6 (5.3)
WA	93	11 (8.5)

State	N	Mean (SD)
VA	189	10.9 (6.3)
AR	70	10.8 (6.4)
KS	57	9.3 (7.5)
IA	67	8.2 (6.6)
DC	86	7.8 (6.6)
MS	90	7.8 (5.1)
OK	21	7.7 (10.1)
NE	166	7.4 (9.7)
MD	38	7.2 (7)
ND	16	6.7 (4.9)
DE	28	6.2 (4.6)
VT	8	5.5 (2.8)
SD	27	5.3 (6)
NH	19	4.8 (3.3)
MT	15	3.6 (3.7)
AK	9	2.3 (3.2)
WY	10	2.2 (3.2)
AS	1	0.6 (0)
GU	5	0.4 (0.4)
MP	2	0 (0)

[1] Each facility's percent of MA was based on patient assignment on January 1, 2018.

Table 10 Percent Missing Data

Variable	Missing
BMI	1.85%
Cause of ESRD	0.8%
Missing 2728	1.16%
Less than 6 Medicare covered months in prior calendar year*	21.48%

*This indicator is used to determine the presence of prevalent comorbidities from Medicare claims.

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

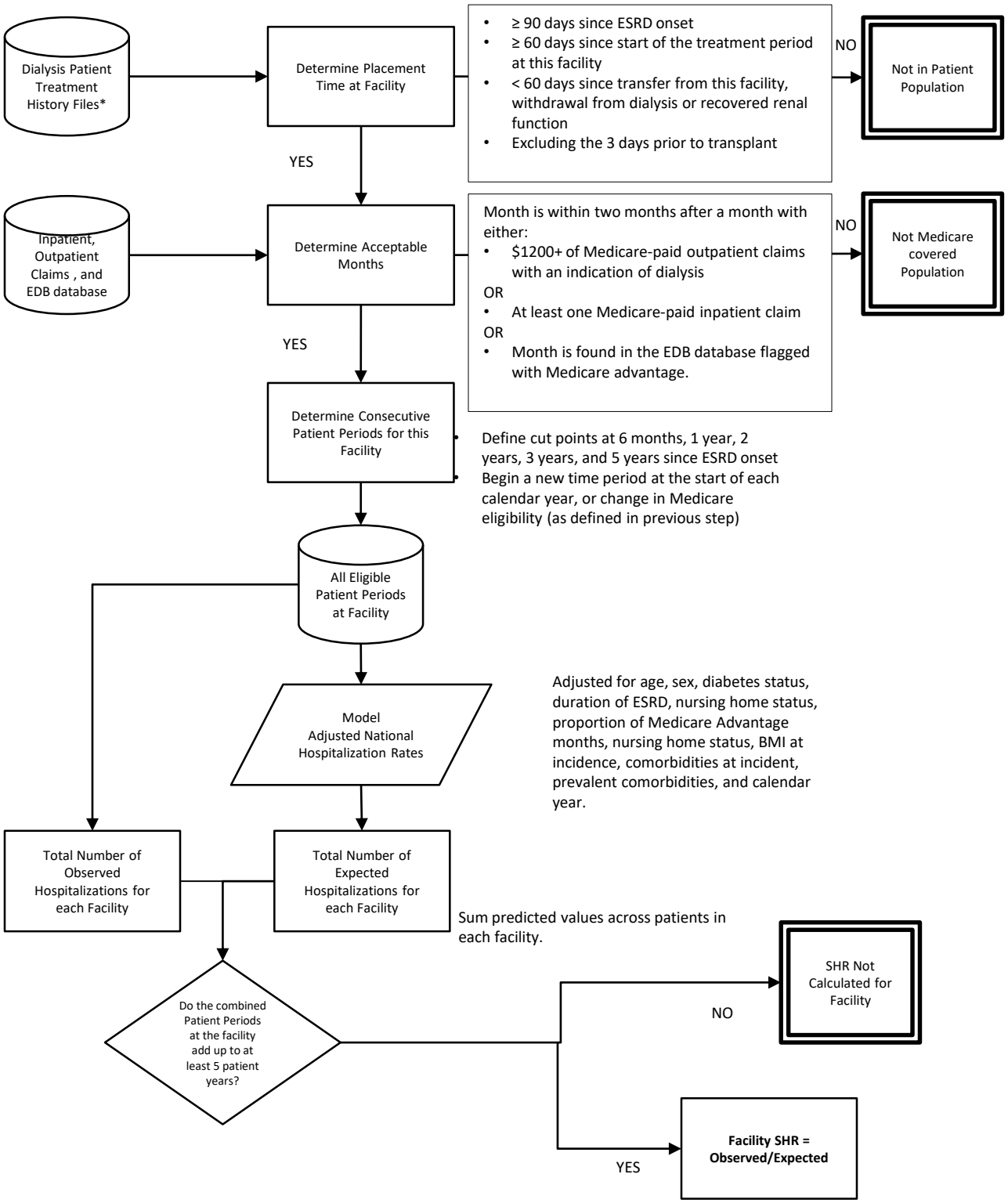
Patients with less than 6 months of Medicare eligible covered months in the prior year were considered as having incomplete prevalent comorbidity information but were not excluded from the model. The percentage of patients with less than 6 months of eligible Medicare covered months is 21.48%, meaning we cannot ascertain prevalent comorbidities for these patients. This is a limitation of relying on Medicare claims for ascertaining comorbidities. However, we mitigate bias in measure performance

scores by risk adjusting for patients with less than 6 months of eligible Medicare covered months in the prior calendar year.

Based on the above results we also modified our method for identifying time at risk in order to better capture the MA population. We add in time at risk for MA patients, which are all months identified as MA (using the EDB) therefore the MA population represented in the measure is not only including those with an inpatient claim (per our standard active Medicare determination) but all MA patients eligible for the measure. Because MA coverage was associated with substantially lower hospitalization, once we added the additional MA at risk time, we include an indicator for the proportion of months with MA. We also restrict to use of inpatient claims for the prevalent comorbidity adjustment. This minimizes risk of biased results at the dialysis facility level.
There is a very low fraction of patients with missing BMI, missing cause of ESRD, and missing form 2728. Missing Cause of ESRD and missing 2728 were accounted for with a category for missingness in the model. Patients with missing BMI were included in the BMI 30+ category.

S.14: Measure Calculation Flowchart

Standardized Hospitalization Ratio: The ratio of observed to expected hospital admissions
Numerator Statement: Number of hospital admissions observed
Denominator Statement: Number of hospital admissions expected based on the national rate for patients with similar characteristics



*Multiple data sources include CMS Consolidated Renal Operations in a Web-enabled Network (CROWNWeb), the CMS Annual Facility Survey (Form CMS-2744), Medicare dialysis and hospital payment records, the CMS Medical Evidence Form (Form CMS-2728), transplant data from the Organ Procurement and Transplant Network (OPTN), the Death Notification Form (Form CMS-2746), the Dialysis Facility Compare (DFC) and the Social Security Death Master File.