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 #: 0369
Corresponding Measures:
De.2. **Measure Title:** Standardized Mortality Ratio for Dialysis Facilities
Co.1.1. **Measure Steward:** Centers for Medicare & Medicaid Services
De.3. **Brief Description of Measure:** Standardized mortality ratio is defined to be the ratio of the number of deaths that occur for Medicare ESRD dialysis patients treated at a particular facility to the number of deaths that would be expected given the characteristics of the dialysis facility's patients and the national norm for dialysis facilities. This measure is calculated as a ratio but can also be expressed as a rate.

When used for public reporting, the measure calculation will be restricted to facilities with less than 3 expected deaths in the reporting year. This restriction is required to ensure patients cannot be identified due to small cell size.
1b.1. **Developer Rationale:** While mortality rates among ESRD patients on chronic dialysis have decreased in the US between 2001 to 2017 (USRDS 2019 Annual Data Report, Executive Summary), dialysis patients continue have higher mortality versus age-matched Medicare beneficiaries without ESRD (USRDS 2018 Annual Data Report, Chapter 5 Mortality). In addition, mortality among ESRD dialysis patients varies across dialysis facilities, even after adjustment for patients' characteristics. An adjusted facility-level mortality, which accounts for differences in patients' characteristics, is one of several important health outcomes used by providers, health consumers, and insurers to evaluate the quality of care provided in dialysis facilities.

Reference: United States Renal Data System. 2019 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, 2019.

Reference: 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 deaths among eligible patients at the facility during the time period.
S.6. **Denominator Statement:** Number of deaths that would be expected among eligible dialysis patients at the facility during the time period, given the national average mortality rate and the patient mix at the facility.
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: May 15, 2008 **Most Recent Endorsement Date:** Dec 09, 2016

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

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

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

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

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

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

0369_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.

While mortality rates among ESRD patients on chronic dialysis have decreased in the US between 2001 to 2017 (USRDS 2019 Annual Data Report, Executive Summary), dialysis patients continue have higher mortality versus age-matched Medicare beneficiaries without ESRD (USRDS 2018 Annual Data Report, Chapter 5 Mortality). In addition, mortality among ESRD dialysis patients varies across dialysis facilities, even after adjustment for patients' characteristics. An adjusted facility-level mortality, which accounts for differences in patients' characteristics, is one of several important health outcomes used by providers, health consumers, and insurers to evaluate the quality of care provided in dialysis facilities.

Reference: United States Renal Data System. 2019 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, 2019.

Reference: 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.*

The average SMR remained stable across years and during the 2015 – 2018 period. The average SMR varied from 1.00 to 1.01. However, within any given year, there was a substantial gap in performance as SMR varied widely across facilities, with the 10th decile being as low as 0.55 and the 90th decile being as high as 1.50.

Distribution of SMRs of all facilities by year (2015-2018):

2015: Facilities = 5,793, Mean SMR = 1.01, Standard Deviation = 0.39, 10th =0.56, 25th = 0.75, 50th = .97, 75th = 1.22, 90th = 1.49

2016: Facilities = 5,977, Mean SMR = 1.01, Standard Deviation =0 .38, 10th = 0.57, 25th = 0.75, 50th = .97, 75th = 1.22, 90th = 1.51

2017: Facilities =6,223, Mean SMR = 1.00, Standard Deviation = 0.39, 10th = 0.55, 25th = 0.75, 50th = .97, 75th = 1.22, 90th = 1.50

2018: Facilities = 6,419, Mean SMR = 1.00, Standard Deviation = 0.39, 10th = 0.55, 25th =0.73, 50th = .95, 75th = 1.22, 90th = 1.48

Across the 4-year SMR (2015-2018): Facilities = 6,971, Mean SMR = 1.01, Standard Deviation = 0.28, 10th = 0.71, 25th = 0.83, 50th = .98, 75th = 1.15, 90th = 1.34

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.*
Data from 2015-2018 show that black patients were at lower risk of mortality compared to white patients (HR = 0.75), as were Native American Asian/Pacific Islander patients, compared to patients of white race (HR = .89, 0.70). Hispanic and unknown ethnicity patients had lower risk of mortality (HR = 0.73 and 0.76, respectively) compared to non-Hispanic patients; and female patients had lower mortality risk than male patients (HR= 0.92). Further, patients unemployed at ESRD incidence have a higher risk of mortality (HR 1.13) compared to those employed at ESRD incidence; dual eligible patients have a nominally lower risk of mortality (HR 0.99). Finally, Area Deprivation Index had no impact on mortality risk (HR 1.0002). More details can be seen in the section on risk adjustment and SDS/SES.

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:** 0369_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:
• Revisions to Prevalent Comorbidity Adjustment:
o Grouped 210 individual ICD-9 prevalent comorbidities into 90 condition groups
o Limited source of prevalent comorbidities to inpatient claims
• Include all time at risk for Medicare Advantage patients
• Updates to parameterization of existing adjustment factors and re-evaluation of interactions
• Implementation of empirical null:
o Harmonize with other standardized measures
o Allow more completely for random variation between facilities
o Facilities are flagged if they have outcomes that are extreme when compared to the variation in outcomes for other facilities of a similar size

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 deaths among eligible patients at the facility during the time 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).
Information on death is obtained from several sources which include the CMS ESRD Program Medical Management Information System, the Death Notification Form (CMS Form 2746), and the Social Security Death Master File. The number of deaths that occurred among eligible dialysis patients during the time period is calculated. This count includes only Medicare patients, as detailed below. It does not include deaths from street drugs or accidents unrelated to treatment as indicated on CMS form 2746 since these deaths are unlikely to have been due to treatment facility characteristics.

S.6. **Denominator Statement** *(Brief, narrative description of the target population being measured)*
Number of deaths that would be expected among eligible dialysis patients at the facility during the time period, given the national average mortality rate and the patient mix at the facility.

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

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

General Inclusion Criteria for Dialysis Patients

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

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

Identifying Facility Treatment Histories for Each Patient

For each patient, we identify the dialysis provider at each point in time. Starting with day 91 after onset of ESRD, we attribute patients to facilities according to the following rules. A patient is attributed to a facility once the patient has been treated there for the past 60 days. When 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 from day 61. In particular, a patient is attributed to their 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 were removed from a facility's analysis upon receiving a transplant. Patients who withdrew from dialysis or recovered renal function remain assigned to their treatment facility for 60 days after withdrawal or recovery.

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

Days at Risk for Each Patient-Record

After patient treatment histories are defined as described above, periods of follow-up time (or patient-records) are created for each patient. A patient-record begins each time the patient is determined to be at a different facility or at the start of each calendar year. The number of days at risk starts over at zero for each patient record so that the number of days at risk for any patient-record is always a number between 0 and 365 (or 366 for leap years). Therefore, a patient who is in one facility for all four years gives rise to four patient-records and is analyzed the same way as would be four separate patients in that facility for one year each.

This measure is limited to Medicare dialysis patients who are either enrolled in Medicare Advantage or who reach a certain threshold of Medicare dialysis and inpatient claims. Specifically, months within a given dialysis patient-period are used for SMR calculation when the patient is enrolled in Medicare Advantage or meets the criterion of being within two months after a month with either: (a) $1200+ of Medicare-paid dialysis claims OR (b) at least one Medicare inpatient claim.

Then we use the number of days at risk in each of these patient-records to calculate the expected number of deaths for that patient-record, and sum the total number of expected deaths during all patient-records at the facility as the expected number of deaths for that facility. Detailed methodology is described in the testing form.

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
0369_Testing_Form_01242020.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 SMR 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 http://www.medicare.gov/dialysisfacilitycompare/ Dialysis Facility Compare http://www.medicare.gov/dialysisfacilitycompare/

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 who are eligible for the measure, and have at least 3 expected deaths during the four year period. For the most recent DFC report, that was 6,971 facilities.

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

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. All Medicare-certified dialysis facilities are eligible for reporting. There is a helpdesk and supporting documentation available to assist with interpretation of the measure results.

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

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.

4a2.2.2. **Summarize the feedback obtained from those being measured.**
Comments received during DFC preview periods tend to be technical nature, asking for clarification on how the SMR is calculated for particular facilities, including questions about patient assignment and application of exclusion and risk adjustment criteria.

4a2.2.3. **Summarize the feedback obtained from other users**
N/A

4a2.3. **Describe how the feedback described in 4a2.2.1 has been considered when developing or revising the measure specifications or implementation, including whether the measure was modified and why or why not.**
The revisions made to the measure specifications during this maintenance review were not directly in response to specific feedback received during public reporting (which, as described above, was more general in nature).

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.
Mortality rates decreased since 2015 (reference year) as evidenced by the hazard ratios for calendar year from the SMR model. The risk of mortality for 2018 was 6% lower compared to 2015 (p-value<0.0001). The risks of mortality in 2016 and 2017 were also lower, respectively, compared to 2015 (p-value <0.0001 for each year).

2015: Reference Category
2016: Coefficient = -0.03, Hazard Ratio= 0.97, P-value = <0.0001
2017: Coefficient = -0.05, Hazard Ratio= 0.95, P-value = <0.0001
2018: Coefficient = -0.06, Hazard Ratio= 0.94, 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)**
1463 : Standardized Hospitalization Ratio for Dialysis Facilities (SHR)
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.**
SMR is a related measure to the standardized hospitalization ratio (SHR) and the standardized readmission ratio (SRR). SMR, and SHR and SRR are harmonized to the target population they measure (Medicare-covered ESRD patients on chronic dialysis), methods (SMR and SHR) and certain risk adjustment factors specific to the ESRD population. SMR and SHR adjust for the same comorbidity risk factors, a similar set of patient characteristics, and use fixed effects in their modeling approach. The differences between SMR and SHR and SRR reflect adjustment for factors specific to the outcome of each respective measure. Both SMR and SHR adjust for a set of prevalent comorbidities (observed in a prior year), however the complete set of comorbidities for SMR differs from SRR. SRR, a measure of hospital utilization adjusts for planned readmissions; and 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 SMR. Only SMR adjusts for state death rates, race, and ethnicity to account for these respective differences related to mortality outcomes and that are deemed outside of a facility's control.

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:** 0369_Flow_Chart.pdf

Contact Information

Co.1 **Measure Steward (Intellectual Property Owner):** Centers for Medicare & Medicaid Services
Co.2 **Point of Contact:** Helen, Dollar-Maples, Helen.Dollar-Maples@cms.hhs.gov, 410-786-7214-

Co.3 **Measure Developer if different from Measure Steward:** University of Michigan Kidney Epidemiology and Cost Center
Co.4 **Point of Contact:** 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
Tufts Medical Center
Boston, MA
Associate Professor of Medicine
Outcomes Monitoring Program, Dialysis Clinic Inc.
Nashville, TN

David Gilbertson, PhD
Co-Director of Epidemiology and Biostatistics
Chronic Disease Research Group
Minneapolis, MN

Eduardo Lacson Jr, MD, MPH
Nephrologist
American Society of Nephrology
Lexington, MA

Jennifer Flythe, MD, MPH
Research Fellow
University of North Carolina at Chapel Hill
Assistant Professor of Medicine
Chapel Hill, NC

Lorien Dalrymple, MD, MPH
Associate Professor
University of California, Davis
Division of Nephrology
Sacramento, CA

Mark Mitsnefes, MD, MS
Professor of Pediatrics
Cincinnati Children's Hospital Medical Center
Program Director
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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:** 1995
Ad.3 **Month and Year of most recent revision:** 04, 2016
Ad.4 **What is your frequency for review/update of this measure?** Annually
Ad.5 **When is the next scheduled review/update for this measure?** 04, 2017

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

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

MEASURE JUSTIFICATION FORM

Project Title:

Standardized Mortality Ratio Measure Maintenance (#0369)

Project Overview:

The Centers for Medicare & Medicaid Services (CMS) has contracted with the University of Michigan Kidney Epidemiology and Cost Center (UM-KECC) to maintain measure endorsed by the National Quality Forum. The contract name is Kidney Disease Quality Measure Development, Maintenance, and Support. The contract number is 75FCMC18D0041, task order number 75FCMC18F0001.

Date:

Information included is current on 9/25/2020

1. Measure Name/Title (NQF Submission Form De.2)

Standardized Mortality Ratio for Dialysis Facilities

2. Type of Measure (NQF Submission Form De.1., NQF Evidence Attachment 1a.1.)

Outcome: Mortality

3. Importance (NQF Importance Tab)

3.1 Evidence to Support the Measure Focus **(for reference only)** (NQF Evidence Attachment Subcriterion 1a.)

3.1.1 This is a Measure of: (should be consistent with type of measure entered in NQF Measure Submission Form De.1) (NQF Evidence Attachment 1a.1)

Outcome: Mortality

3.1.2 Logic Model (NQF Evidence Attachment 1a.2)

2011 Submission

The Standardized Mortality Ratio (SMR) is used by ESRD state surveyors in conjunction with other standard criteria for prioritizing and selecting facilities to survey. This patient survival classification measure is reported publicly on the DFC web site to assist patients in selecting dialysis facilities.

2016 Submission

There are numerous dialysis facility processes of care that can influence the risk of patient mortality. 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 death.

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

2019/2020 Submission: no change to the previous submission

3.1.3 Value and Meaningfulness (NQF Evidence Attachment 1a.3)

N/A

3.1.4 Empirical Data (for outcome measures) – as applicable (NQF Evidence Attachment 1a.2)

2011 Submission

This was not a question on the 2011 Submission Form.

2016 Submission:

ESRD patients on chronic dialysis experience all cause mortality far in excess of age matched controls [1]. Patients in some dialysis facilities have consistently higher mortality than patients in other facilities, even after controlling for multiple patient characteristics [2]. Selection of dialysis modality, sometimes the result of dialysis facility practices, likely influences mortality [3]. Furthermore, mortality from certain conditions resulting from kidney failure and chronic dialysis care, including uremic toxin accumulation, volume overload/HTN and its treatment, bone/mineral disease, and infections related to dialysis access, have been described in detail [4-6].

Specific dialysis practices have been identified for several of these ESRD-related conditions that can improve patient survival and morbidity, including provision of adequate small solute clearance [7], control of total body volume while guarding against rapid ultrafiltration [8-11] and appropriate management of mineral and bone disorders [12-14]. In addition, improved infection prevention efforts by dialysis providers can result in reduced infection-related hospitalization and mortality [15-20].

2019/2020 Submission:

ESRD patients on chronic dialysis experience all-cause mortality far in excess of age matched controls in the general and Medicare populations [1]. Mortality rates across dialysis facilities vary, even after controlling for multiple patient characteristics and comorbidities [2]. Selection of dialysis modality, sometimes the result of dialysis facility practices, likely influences mortality [3]. Furthermore, mortality is associated with certain conditions resulting from kidney failure and chronic dialysis care, including uremic toxin accumulation, volume overload/HTN and its treatment, bone/mineral disease, and infections related to dialysis access, have been described in detail [4-6].

Specific dialysis practices have been identified for several of these ESRD-related conditions that can improve patient survival and morbidity, including provision of adequate small solute clearance [7], control of total body volume while guarding against rapid ultrafiltration [8-11] and appropriate management of mineral and bone disorders [12-14]. In addition, improved infection prevention efforts by dialysis providers can result in reduced infection-related hospitalization and mortality [15-20].

Additional studies have bolstered the importance of fluid management in improving patient survival [24, 26, 37]. Rescheduling missed dialysis treatments [21], as well as providing longer treatment times at dialysis initiation [33], while being mindful to preserve residual kidney function [30] all have the potential to reduce patient mortality. Nutrition counseling, and how the interdisciplinary team manages potassium [38], phosphorus [31] and encourages healthy eating habits with fruits/vegetables [39] also impact patient outcomes. Sustained efforts at influenza vaccinations can impact mortality [32]. Lastly, in the midst of a national opioid epidemic, dialysis patient are at particularly increased risk of adverse outcomes and careful attention is needed to avoid excess mortality [25].

References (all submissions, with recent references 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]. Kalbfleisch J, Wolfe R, Bell S, Sun R, Messana J, Shearon T, Ashby V, Padilla R, Zhang M, Turenne M, Pearson J, Dahlerus C, Li Y. Risk Adjustment and the Assessment of Disparities in Dialysis Mortality Outcomes. J Am Soc Nephrol. 2015; Nov;26(11):2641-5.

Abstract: Standardized mortality ratios (SMRs) reported by Medicare compare mortality at individual dialysis facilities with the national average, and are currently adjusted for race. However, whether the adjustment for race obscures or clarifies disparities in quality of care for minority groups is unknown. Cox model-based SMRs were computed with and without adjustment for patient race for 5920 facilities in the United States during 2010. The study population included virtually all patients treated with dialysis during this period. Without race adjustment, facilities with higher proportions of black patients had better survival outcomes; facilities with the highest percentage of black patients (top 10%) had overall mortality rates approximately 7% lower than expected. After adjusting for within-facility racial differences, facilities with higher proportions of black patients had poorer survival outcomes among black and non-black patients; facilities with the highest percentage of black patients (top 10%) had mortality rates approximately 6% worse than expected. In conclusion, accounting for within-facility racial differences in the computation of SMR helps to clarify disparities in quality of health care among patients with ESRD. The adjustment that accommodates within-facility comparisons is key, because it could also clarify relationships between patient characteristics and health care provider outcomes in other settings.

[3]. Weinhandl ED, Nieman KM, Gilbertson DT, Collins AJ. Hospitalization in daily home hemodialysis and matched thrice-weekly in-center hemodialysis patients. Am J Kidney Dis. 2015 Jan;65(1):98-108.

BACKGROUND: Cardiovascular disease is a common cause of hospitalization in dialysis patients. Daily hemodialysis improves some parameters of cardiovascular function, but whether it associates with lower hospitalization risk is unclear.

STUDY DESIGN: Observational cohort study using US Renal Data System data.

SETTING & PARTICIPANTS: Medicare-enrolled daily (5 or 6 sessions weekly) home hemodialysis (HHD) patients initiating NxStage System One use from January 1, 2006, through December 31, 2009, and contemporary thrice-weekly in-center hemodialysis patients, matched 5 to 1.

PREDICTOR: Daily HHD or thrice-weekly in-center hemodialysis.

OUTCOMES & MEASUREMENTS: All-cause and cause-specific hospital admissions, hospital readmissions, and hospital days assessed from Medicare Part A claims.

RESULTS: For 3,480 daily HHD and 17,400 thrice-weekly in-center hemodialysis patients in intention-to-treat analysis, the HR of all-cause admission for daily HHD versus in-center hemodialysis was 1.01 (95%CI, 0.98-1.03). Cause-specific admission HRs were 0.89 (95%CI, 0.86-0.93) for cardiovascular disease, 1.18 (95%CI, 1.13-1.23) for infection, 1.01 (95%CI, 0.93-1.09) for vascular access dysfunction, and 1.02 (95%CI, 0.99-1.06) for other morbidity. Regarding cardiovascular disease, first admission and readmission HRs for daily HHD versus in-center hemodialysis were 0.91 and 0.87, respectively. Regarding infection, first admission and readmission HRs were 1.35 and 1.03, respectively. Protective associations of daily HHD with heart failure and hypertensive disease were most pronounced, as were adverse associations of daily HHD with bacteremia/sepsis, cardiac infection, osteomyelitis, and vascular access infection.

LIMITATIONS: Results may be confounded by unmeasured factors, including vascular access type; information about dialysis frequency, duration, and dose was lacking; causes of admission may be misclassified; results may not apply to patients without Medicare coverage.

CONCLUSIONS: All-cause hospitalization risk was similar in daily HHD and thrice-weekly in-center hemodialysis patients. However, risk of cardiovascular-related admission was lower with daily HHD, and risk of infection-related admission was higher. More attention should be afforded to infection in HHD patients.

[4]. Himmelfarb J, Ikizler T. Hemodialysis N Engl J. 2010 Nov; 363:1833–1845.

Abstract: Fifty years ago, Belding Scribner and his colleagues at the University of Washington developed a blood-access device using Teflon-coated plastic tubes, which facilitated the use of repeated hemodialysis as a life-sustaining treatment for patients with uremia.1,2 The introduction of the Scribner shunt, as it became known, soon led to the development of a variety of surgical techniques for the creation of arteriovenous fistulas and grafts. Consequently, hemodialysis has made survival possible for more than a million people throughout the world who have end-stage renal disease (ESRD) with limited or no kidney function. The expansion of dialysis into a form of long-term renal-replacement therapy transformed the field of nephrology and also created a new area of medical science, which has been

called the physiology of the artificial kidney. This review describes the medical, social, and economic evolution of hemodialysis therapy.

[5]. Kliger AS. Maintaining Safety in the Dialysis Facility. Clin J Am Soc Nephrol. 2015 Apr 7;10(4):688-95.

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.

[6]. Hung AM, Hakim RM. Dialysate and Serum Potassium in Hemodialysis. Am J Kidney Dis. 2015 Jul;66(1):125-32.

Abstract: Most patients with end-stage renal disease depend on intermittent hemodialysis to maintain levels of serum potassium and other electrolytes within a normal range. However, one of the challenges has been the safety of using a low-potassium dialysate to achieve that goal, given the concern about the effects that rapid and/or large changes in serum potassium concentrations may have on cardiac electrophysiology and arrhythmia. Additionally, in this patient population, there is a high prevalence of structural cardiac changes and ischemic heart disease, making them even more susceptible to acute arrhythmogenic triggers. This concern is highlighted by the knowledge that about two-thirds of all cardiac deaths in dialysis are due to sudden cardiac death and that sudden cardiac death accounts for 25% of the overall death for end-stage renal disease. Developing new approaches and practice standards for potassium removal during dialysis, as well as understanding other modifiable triggers of sudden cardiac death, such as other electrolyte components of the dialysate (magnesium and calcium), rapid ultrafiltration rates, and safety of a number of medications (ie, drugs that prolong the QT interval or use of digoxin), are critical in order to decrease the unacceptably high cardiac mortality experienced by hemodialysis-dependent patients.

[7]. Port FK, Ashby VB, Dhingra RK, Roys EC, Wolfe RA: Dialysis dose and body mass index are strongly associated with survival in hemodialysis patients. J Am Soc Nephrol 13:1061-1066, 2002

Abstract: Low dose of hemodialysis (HD) and small body size are independent risk factors for mortality. Recent changes in clinical practice, toward higher HD doses and use of more high-flux dialyzers, suggest the need to redetermine the dose level above which no benefit from higher dose can be observed. Data were analyzed from 45,967 HD patients starting end-stage renal disease (ESRD) therapy during April 1, 1997, through December 31, 1998. Data from Health Care Financing Administration (HCFA) billing records during months 10 to 15 of ESRD were used to classify each patient into one of five categories of HD dose by urea reduction ratio (URR) ranging from <60% to >75%. Cox regression models were used to calculate relative risk (RR) of mortality after adjustment for demographics, body mass index (BMI), and 18 comorbid conditions. Of the three body-size groups, the lowest BMI group had a 42% higher mortality risk than the highest BMI tertile. In each of three body-size groups by BMI, the RR was 17%,

17%, and 19% lower per 5% higher URR category among groups with small, medium, and large BMI, respectively (P < 0.0001 for each group). Patients treated with URR >75% had a substantially lower RR than patients treated with URR 70 to 75% (P < 0.005 each, for medium and small BMI groups). It is concluded that a higher dialysis dose, substantially above the Dialysis Outcomes Quality Initiative guidelines (URR >65%), is a strong predictor of lower patient mortality for patients in all body-size groups. Further reductions in mortality might be possible with increased HD dose.

[8]. Saran R, Bragg-Gresham JL, Levin NW, Twardowski ZJ, Wizemann V, Saito A, Kimata N, Gillespie BW, Combe C, Bommer J, Akiba T, Mapes DL, Young EW, Port FK. Longer Treatment Time and Slower Ultrafiltration in Hemodialysis: Associations With Reduced Mortality in the DOPPS. Kidney Int. 2006 Apr;69(7):1222-8.

Abstract: Longer treatment time (TT) and slower ultrafiltration rate (UFR) are considered advantageous for hemodialysis (HD) patients. The study included 22,000 HD patients from seven countries in the Dialysis Outcomes and Practice Patterns Study (DOPPS). Logistic regression was used to study predictors of TT > 240 min and UFR > 10 ml/h/kg bodyweight. Cox regression was used for survival analyses. Statistical adjustments were made for patient demographics, comorbidities, dose of dialysis (Kt/V), and body size. Europe and Japan had significantly longer (P < 0.0001) average TT than the US (232 and 244 min vs 211 in DOPPS I; 235 and 240 min vs 221 in DOPPS II). Kt/V increased concomitantly with TT in all three regions with the largest absolute difference observed in Japan. TT > 240 min was independently associated with significantly lower relative risk (RR) of mortality (RR = 0.81; P = 0.0005). Every 30 min longer on HD was associated with a 7% lower RR of mortality (RR = 0.93; P < 0.0001). The RR reduction with longer TT was greatest in Japan. A synergistic interaction occurred between Kt/V and TT (P = 0.007) toward mortality reduction. UFR > 10 ml/h/kg was associated with higher odds of intradialytic hypotension (odds ratio = 1.30; P = 0.045) and a higher risk of mortality (RR = 1.09; P = 0.02). Longer TT and higher Kt/V were independently as well as synergistically associated with lower mortality. Rapid UFR during HD was also associated with higher mortality risk. These results warrant a randomized clinical trial of longer dialysis sessions in thrice-weekly HD.

[9]. FHN Trial Group, Chertow GM, Levin NW, Beck GJ, Depner TA, Eggers PW, Gassman JJ, Gorodetskaya I, Greene T, James S, Larive B, Lindsay RM, Mehta RL, Miller B, Ornt DB, Rajagopalan S, Rastogi A, Rocco MV, Schiller B, Sergeyeva O, Schulman G, Ting GO, Unruh ML, Star RA, Kliger AS. In-center hemodialysis six times per week versus three times per week. N Engl J Med. 2010 Dec 9;363(24):2287-300.

BACKGROUND: In this randomized clinical trial, we aimed to determine whether increasing the frequency of in-center hemodialysis would result in beneficial changes in left ventricular mass, self-reported physical health, and other intermediate outcomes among patients undergoing maintenance hemodialysis.

METHODS: Patients were randomly assigned to undergo hemodialysis six times per week (frequent hemodialysis, 125 patients) or three times per week (conventional hemodialysis, 120 patients) for 12 months. The two coprimary composite outcomes were death or change (from baseline to 12 months) in left ventricular mass, as assessed by cardiac magnetic resonance imaging, and death or change in the physical-health composite score of the RAND 36-item health survey. Secondary outcomes included

cognitive performance; self-reported depression; laboratory markers of nutrition, mineral metabolism, and anemia; blood pressure; and rates of hospitalization and of interventions related to vascular access.

RESULTS: Patients in the frequent-hemodialysis group averaged 5.2 sessions per week; the weekly standard Kt/V(urea) (the product of the urea clearance and the duration of the dialysis session normalized to the volume of distribution of urea) was significantly higher in the frequent-hemodialysis group than in the conventional-hemodialysis group (3.54±0.56 vs. 2.49±0.27). Frequent hemodialysis was associated with significant benefits with respect to both coprimary composite outcomes (hazard ratio for death or increase in left ventricular mass, 0.61; 95% confidence interval [CI], 0.46 to 0.82; hazard ratio for death or a decrease in the physical-health composite score, 0.70; 95% CI, 0.53 to 0.92). Patients randomly assigned to frequent hemodialysis were more likely to undergo interventions related to vascular access than were patients assigned to conventional hemodialysis (hazard ratio, 1.71; 95% CI, 1.08 to 2.73). Frequent hemodialysis was associated with improved control of hypertension and hyperphosphatemia. There were no significant effects of frequent hemodialysis on cognitive performance, self-reported depression, serum albumin concentration, or use of erythropoiesis-stimulating agents.

CONCLUSIONS: Frequent hemodialysis, as compared with conventional hemodialysis, was associated with favorable results with respect to the composite outcomes of death or change in left ventricular mass and death or change in a physical-health composite score but prompted more frequent interventions related to vascular access. (Funded by the National Institute of Diabetes and Digestive and Kidney Diseases and others; ClinicalTrials.gov number, NCT00264758.).

[10]. Flythe JE, Curhan GC, Brunelli SM. Disentangling the Ultrafiltration Rate–Mortality Association: The Respective Roles of Session Length and Weight Gain. Clin J Am Soc Nephrol. 2013 Jul;8(7):1151-61

BACKGROUND AND OBJECTIVES: Rapid ultrafiltration rate is associated with increased mortality among hemodialysis patients. Ultrafiltration rates are determined by interdialytic weight gain and session length. Although both interdialytic weight gain and session length have been linked to mortality, the relationship of each to mortality, independent of the other, is not adequately defined. This study was designed to evaluate whether shorter session length independent of weight gain and larger weight gain independent of session length are associated with increased mortality.

DESIGN, SETTING, PARTICIPANTS, & MEASUREMENTS: Data were taken from a national cohort of 14,643 prevalent, thrice-weekly, in-center hemodialysis patients dialyzing from 2005 to 2009 (median survival time, 25 months) at a single dialysis organization. Patients with adequate urea clearance and delivered dialysis session ≥240 and <240 minutes were pair-matched on interdialytic weight gain (n=1794), and patients with weight gain ≤3 and >3 kg were pair-matched on session length (n=2114); mortality associations were estimated separately.

RESULTS: Compared with delivered session length ≥240, session length <240 minutes was associated with increased all-cause mortality (adjusted hazard ratio [95% confidence interval], 1.32 [1.03 to 1.69]). Compared with weight gain ≤3, weight gain >3 kg was associated with increased mortality (1.29 [1.01 to

1.65]). The associations were consistent across strata of age, sex, weight, and weight gain and session length. Secondary analyses demonstrated dose-response relationships between both and mortality.

CONCLUSIONS: Among patients with adequate urea clearance, shorter dialysis session length and greater interdialytic weight gain are associated with increased mortality; thus, both are viable targets for directed intervention.

[11]. Weiner DE, Brunelli SM, Hunt A, Schiller B, Glassrock R, Maddux FW, Johnson D, Parker T, Nissenson A. Improving clinical outcomes among hemodialysis patients: a proposal for a "volume first" approach from the chief medical officers of US dialysis providers. Am J Kidney Dis. 2014 Nov;64(5):685-95.

Abstract: Addressing fluid intake and volume control requires alignment and coordination of patients, providers, dialysis facilities, and payers, potentially necessitating a "Volume First" approach. This article reports the consensus opinions achieved at the March 2013 symposium of the Chief Medical Officers of 14 of the largest dialysis providers in the United States. These opinions are based on broad experience among participants, but often reinforced by only observational and frequently retrospective studies, highlighting the lack of high-quality clinical trials in nephrology. Given the high morbidity and mortality rates among dialysis patients and the absence of sufficient trial data to guide most aspects of hemodialysis therapy, participants believed that immediate attempts to improve care based on quality improvement initiatives, physiologic principles, and clinical experiences are warranted until such time as rigorous clinical trial data become available. The following overarching consensus opinions emerged. (1) Extracellular fluid status should be a component of sufficient dialysis, such that approaching normalization of extracellular fluid volume should be a primary goal of dialysis care. (2) Fluid removal should be gradual and dialysis treatment duration should not routinely be less than 4 hours without justification based on individual patient factors. (3) Intradialytic sodium loading should be avoided by incorporating dialysate sodium concentrations set routinely in the range of 134-138 mEq/L, avoidance of routine use of sodium modeling, and avoidance of hypertonic saline solution. (4) Dietary counseling should emphasize sodium avoidance.

[12]. 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. Clin J Am Soc Nephrol. 2013 Dec;8(12):2132-40.

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.

[13]. Pun PH, Horton JR, Middleton JP. Dialysate calcium concentration and the risk of sudden cardiac arrest in hemodialysis patients. Clin J Am Soc Nephrol. 2013 May;8(5):797-803.

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.

[14]. 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. 2015 Jan 7;10(1):90-7.

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.

[15]. Gilbertson DT, Unruh M, McBean AM, Kausz AT, Snyder JJ, Collins AJ. Influenza vaccine delivery and effectiveness in end-stage renal disease. Kidney Int. 2003 Feb;63(2):738-43.

BACKGROUND: Influenza vaccination rates in the general population have been associated with improved outcomes, yet high-risk populations, such as end-stage renal disease (ESRD) patients, have received little attention in determining the potential benefits. This report assessed the frequency and effectiveness of influenza vaccination, while also assessing disparities in vaccination rates in the ESRD population.

METHODS: Using the United States Renal Data System research files containing claims for all Medicare ESRD patients, vaccination rates and outcomes among vaccinated and unvaccinated persons for the 1997 to 1998 and 1998 to 1999 influenza seasons were compared after adjustment for baseline demographic factors and health characteristics.

RESULTS: Vaccination rates in the ESRD population were less than 50% for each season. Influenza vaccination rates were lower in non-whites, women, younger patients, and peritoneal dialysis patients. Influenza vaccination was associated with a lower risk for hospitalization and death.

CONCLUSIONS: Despite universal coverage of free influenza vaccination, the ESRD population had a less than 50% vaccination rate for the years 1997 to 1998 and 1998 to 1999 as demonstrated by Medicare billing data. Substantial differences were found in vaccination rates among non-whites and peritoneal dialysis patients. This study confirms that the ESRD populations benefit from influenza vaccination, suggesting that dialysis providers should take advantage of all opportunities to immunize this high-risk group.

[16]. Rosenblum A, Wang W, Ball LK, Latham C, Maddux FW, Lacson E Jr. Hemodialysis catheter care strategies: a cluster-randomized quality improvement initiative. Am J Kidney Dis. 2014 Feb;63(2):259-67.

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.

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

Abstract: 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.

[18]. Dalrymple LS, Mu Y, Romano PS, Nguyen DV, Chertow GM, Delgado C, Grimes B, Kaysen GA, Johansen KL. Outcomes of infection-related hospitalization in Medicare beneficiaries receiving in-center hemodialysis. Am J Kidney Dis. 2015 May;65(5):754-62.

BACKGROUND: Infection is a common cause of hospitalization in adults receiving hemodialysis. Limited data are available about downstream events resulting from or following these hospitalizations.

STUDY DESIGN: Retrospective cohort study using the US Renal Data System.

SETTING & PARTICIPANTS: Medicare beneficiaries initiating in-center hemodialysis therapy in 2005 to 2008.

FACTORS: Demographics, dual Medicare/Medicaid eligibility, body mass index, comorbid conditions, initial vascular access type, nephrology care prior to dialysis therapy initiation, residence in a care facility, tobacco use, biochemical measures, and type of infection.

OUTCOMES: 30-day hospital readmission or death following first infection-related hospitalization.

RESULTS: 60,270 Medicare beneficiaries had at least one hospitalization for infection. Of those who survived the initial hospitalization, 15,113 (27%) were readmitted and survived the 30 days following hospital discharge, 1,624 (3%) were readmitted to the hospital and then died within 30 days of discharge, and 2,425 (4%) died without hospital readmission. Complications related to dialysis access, sepsis, and heart failure accounted for 12%, 9%, and 7% of hospital readmissions, respectively. Factors associated with higher odds of 30-day readmission or death without readmission included non-Hispanic ethnicity, lower serum albumin level, inability to ambulate or transfer, limited nephrology care prior to dialysis therapy, and specific types of infection. In comparison, older age, select comorbid conditions, and institutionalization had stronger associations with death without readmission than with readmission.

LIMITATIONS: Findings limited to Medicare beneficiaries receiving in-center hemodialysis.

CONCLUSIONS: Hospitalizations for infection among patients receiving in-center hemodialysis are associated with exceptionally high rates of 30-day hospital readmission and death without readmission.

[19]. 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.

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.

[20]. Gilbertson DT, Wetmore JB. Infections Requiring Hospitalization in Patients on Hemodialysis. Clin J Am Soc Nephrol. 2015 Dec 7;10(12):2101-3.

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%.

[21] Dena E. Cohen, Kathryn S. Gray, Carey Colson, David B. Van Wyck, Francesca Tentori, and

Steven M. Brunelli. Impact of Rescheduling a Missed Hemodialysis Treatment on Clinical Outcomes.

Kidney Medicine. Volume 2, Issue 1, January–February 2020, Pages 12-19

Rationale & Objective: Among patients treated with in-center hemodialysis (HD), missed treatments are associated with higher subsequent rates of hospitalization and other adverse outcomes compared with attending treatment. The objective of this study was to determine whether and to what degree attending a rescheduled treatment on the day following a missed treatment ameliorates these risks.

Study Design: Retrospective, observational.

Setting & Participants: Included patients were those who were, as of any of 12 index dates during 2014, adult Medicare beneficiaries treated with in-center HD (vintage ≥ 90 days) on a Monday/Wednesday/Friday schedule.

Exposure: Treatment attendance on the index date and the subsequent day.

Outcomes: Hospital admissions, emergency department visits, mortality, blood pressure, and anemia measures, considered during the 7- and 30-day periods following exposure.

Analytical Approach: In parallel analyses, patients who missed or rescheduled treatment were each matched (1:5) to patients who attended treatment on the index date on the basis of index day of week and propensity score. Within the matched cohorts, outcomes were compared across exposures using repeated-measures generalized linear models.

Results: Compared with attending treatment (N = 19,260), a missed treatment (N = 3,852) was associated with a 2.09-fold higher rate of hospitalization in the subsequent 7 days; a rescheduled treatment (N = 2,128) was associated with a 1.68-fold higher rate of hospitalization than attending (N = 10,640). Compared with attending treatment, hospitalization rates were 1.39- and 1.28-fold higher

among patients who missed and rescheduled treatment, respectively, during the 30-day outcome period. Emergency department visits followed a similar pattern of associations as hospitalization. No statistically significant associations were observed with respect to mortality for either missed or rescheduled treatments compared with attending treatment.

Limitations: Possible influence of unmeasured confounding; unknown generalizability to patients with non-Medicare insurance.

Conclusions: Attending a rescheduled in-center HD treatment attenuates but does not fully mitigate the adverse effects of a missed treatment.

[22] Abdulkareem Agunbiade , Abhijit Dasgupta , Michael M Ward. Racial/Ethnic Differences in Dialysis Discontinuation and Survival After Hospitalization for Serious Conditions Among Patients on Maintenance Dialysis. J Am Soc Nephrol, 31 (1), 149-160 Jan 2020.

Background: Racial and ethnic minorities on dialysis survive longer than whites, and are less likely to discontinue dialysis. Both differences have been attributed by some clinicians to better health among minorities on dialysis.

Methods: To test if racial and ethnic differences in dialysis discontinuation reflected better health, we conducted a retrospective cohort study of survival and dialysis discontinuation among patients on maintenance dialysis in the US Renal Data System after hospitalization for either stroke (n=60,734), lung cancer (n=4100), dementia (n=40,084), or failure to thrive (n=42,950) between 2003 and 2014. We examined the frequency of discontinuation of dialysis and used simulations to estimate survival in minorities relative to whites if minorities had the same pattern of dialysis discontinuation as whites.

Results: Blacks, Hispanics, and Asians had substantially lower frequencies of dialysis discontinuation than whites in each hospitalization cohort. Observed risks of mortality were also lower for blacks, Hispanics, and Asians. In simulations that assigned discontinuation patterns similar to those found among whites across racial and ethnic groups, differences in survival were markedly attenuated and hazard ratios approached 1.0. Survival and dialysis discontinuation frequencies among American Indians and Alaska Natives were close to those of whites.

Conclusions: Racial and ethnic differences in dialysis discontinuation were present among patients hospitalized with similar health events. Among these patients, survival differences between racial and ethnic minorities and whites were largely attributable to differences in the frequency of discontinuation of dialysis.

[23] Fozia Ajmal, Janice C Probst, John M Brooks, James W Hardin, Zaina Qureshi, Tazeen H Jafar . Freestanding Dialysis Facility Quality Incentive Program Scores and Mortality Among Incident Dialysis Patients in the United States. Am J Kidney Dis, 75 (2), 177-186 Feb 2020.

Rationale & objective: The Centers for Medicare & Medicaid Services introduced the Quality Incentive Program (QIP) along with the bundled payment reform to improve the quality of dialysis care in the United States. The QIP has been criticized for using easily obtained laboratory indicators without patient-centered measures and for a lack of evidence for an association between QIP indicators and patient outcomes. This study examined the association between dialysis facility QIP performance scores and survival among patients after initiation of dialysis.

Study design: Retrospective cohort study.

Setting & participants: Study participants included 84,493 patients represented in the US Renal Disease System's patient-level data who had initiated dialysis between January 1, 2013, and December 1, 2013, and who did not, during the first 90 days after dialysis initiation, die, receive a transplant, or become lost to follow-up. Patients were followed up for the study outcome through March 31, 2014.

Predictor: Dialysis facility QIP scores.

Outcome: Mortality.

Analytical approach: Using a unique facility identifier, we linked Medicare freestanding dialysis facility data from 2015 with US Renal Disease System patient-level data. Kaplan-Meier product limit estimator was used to describe the survival of study participants. Cox proportional hazards regression was used to assess the multivariable association between facility performance scores and patient survival.

Results: Excluding patients who died during the first 90 days of dialysis, 11.8% of patients died during an average follow-up of 5 months. Facilities with QIP scores<45 (HR, 1.39; 95% CI, 1.15-1.68) and 45 to<60 (HR, 1.21; 95% CI, 1.10-1.33) had higher patient mortality rates than facilities with scores≥90.

Limitations: Because the Centers for Medicare & Medicaid Services have revised QIP criteria each year, the findings may not relate to years other than those studied.

Conclusions: Dialysis facilities characterized by lower QIP scores were associated with higher rates of patient mortality. These findings need to be replicated to assess their consistency over time.

[24] Magdalene M Assimon, Julia B Wenger, Lily Wang, Jennifer E Flythe. Ultrafiltration Rate and Mortality in Maintenance Hemodialysis Patients. Am J Kidney Dis, 68 (6), 911-922 Dec 2016.

Background: Observational data have demonstrated an association between higher ultrafiltration rates and greater mortality among hemodialysis patients. Prior studies were small and did not consider potential differences in the association across body sizes and other related subgroups. No study has investigated ultrafiltration rates normalized to anthropometric measures beyond body weight. Also, potential methodological shortcomings in prior studies have led to questions about the veracity of the ultrafiltration rate-mortality association.

Study design: Retrospective cohort.

Setting & participants: 118,394 hemodialysis patients dialyzing in a large dialysis organization, 2008 to 2012.

Predictors: Mean 30-day ultrafiltration rates were dichotomized at 13 and 10mL/h/kg, separately and categorized using various cutoff points. Ultrafiltration rates normalized to body weight, body mass index, and body surface area were investigated.

Outcomes: All-cause mortality.

Measurements: Multivariable survival models were used to estimate the association between ultrafiltration rate and all-cause mortality.

Results: At baseline, 21,735 (18.4%) individuals had ultrafiltration rates > 13mL/h/kg and 48,529 (41.0%) had ultrafiltration rates > 10mL/h/kg. Median follow-up was 2.3 years, and the mortality rate was 15.3 deaths/100 patient-years. Compared with ultrafiltration rates ≤ 13mL/h/kg, ultrafiltration rates > 13mL/h/kg were associated with greater mortality (adjusted HR, 1.31; 95% CI, 1.28-1.34). Compared with ultrafiltration rates ≤ 10mL/h/kg, ultrafiltration rates > 10mL/h/kg were associated with greater mortality (adjusted HR, 1.22; 95% CI, 1.20-1.24). Findings were consistent across subgroups of sex, race, dialysis vintage, session duration, and body size. Higher ultrafiltration rates were associated with greater mortality when normalized to body weight, body mass index, and body surface area.

Limitations: Residual confounding cannot be excluded given the observational study design.

Conclusions: Regardless of the threshold implemented, higher ultrafiltration rate was associated with greater mortality in the overall study population and across key subgroups. Randomized controlled trials are needed to investigate whether ultrafiltration rate reduction improves clinical outcomes.

[25] Kimmel PL, Fwu CW, Abbott KC, Eggers AW, Kline PP, Eggers PW. J Am Soc Nephrol. 2017 Dec;28(12):3658-3670. doi: 10.1681/ASN.2017010098. Epub 2017 Sep 21. Opioid Prescription, Morbidity, and Mortality in United States Dialysis Patients.

Aggressive pain treatment was advocated for ESRD patients, but new Centers for Disease Control and Prevention guidelines recommend cautious opioid prescription. Little is known regarding outcomes associated with ESRD opioid prescription. We assessed opioid prescriptions and associations between opioid prescription and dose and patient outcomes using 2006-2010 US Renal Data System information in patients on maintenance dialysis with Medicare Part A, B, and D coverage in each study year (n=671,281, of whom 271,285 were unique patients). Opioid prescription was confirmed from Part D prescription claims. In the 2010 prevalent cohort (n=153,758), we examined associations of opioid prescription with subsequent all-cause death, dialysis discontinuation, and hospitalization controlled for demographics, comorbidity, modality, and residence. Overall, >60% of dialysis patients had at least one opioid prescription every year. Approximately 20% of patients had a chronic (≥90-day supply) opioid prescription each year, in 2010 usually for hydrocodone, oxycodone, or tramadol. In the 2010 cohort, compared with patients without an opioid prescription, patients with short-term (1-89 days) and chronic opioid prescriptions had increased mortality, dialysis discontinuation, and hospitalization. All opioid drugs associated with mortality; most associated with worsened morbidity. Higher opioid

doses correlated with death in a monotonically increasing fashion. We conclude that opioid drug prescription is associated with increased risk of death, dialysis discontinuation, and hospitalization in dialysis patients. Causal relationships cannot be inferred, and opioid prescription may be an illness marker. Efforts to treat pain effectively in patients on dialysis yet decrease opioid prescriptions and dose deserve consideration.

[26] Zoccali C, Moissl U, Chazot C, Mallamaci F, Tripepi G, Arkossy O, Wabel P, Stuard S.

J Am Soc Nephrol. 2017 Aug;28(8):2491-2497. doi: 10.1681/ASN.2016121341. Epub 2017 May 4. Chronic Fluid Overload and Mortality in ESRD.

Sustained fluid overload (FO) is considered a major cause of hypertension, heart failure, and mortality in patients with ESRD on maintenance hemodialysis. However, there has not been a cohort study investigating the relationship between chronic exposure to FO and mortality in this population. We studied the relationship of baseline and cumulative FO exposure over 1 year with mortality in 39,566 patients with incident ESRD in a large dialysis network in 26 countries using whole-body bioimpedance spectroscopy to assess fluid status. Analyses were applied across three discrete systolic BP (syst-BP) categories (<130, 130-160, and >160 mmHg), with nonoverhydrated patients with syst-BP=130-160 mmHg as the reference category; >200,000 FO measurements were performed over follow-up. Baseline FO value predicted excess risk of mortality across syst-BP categories (<130 mmHg: hazard ratio [HR], 1.51; 95% confidence interval [95% CI], 1.38 to 1.65; 130-160 mmHg: HR, 1.25; 95% CI, 1.16 to 1.36; >160 mmHg: HR, 1.30; 95% CI, 1.19 to 1.42; all P<0.001). However, cumulative 1-year FO exposure predicted a higher death risk (P<0.001) across all syst-BP categories (<130 mmHg: HR, 1.94; 95% CI, 1.68 to 2.23; 130-160 mmHg: HR, 1.51; 95% CI, 1.35 to 1.69; >160 mmHg: HR, 1.62; 95% CI, 1.39 to 1.90). In conclusion, chronic exposure to FO in ESRD is a strong risk factor for death across discrete BP categories. Whether treatment policies that account for fluid status monitoring are preferable to policies that account solely for predialysis BP measurements remains to be tested in a clinical trial.

[27] Ku E, Yang W, McCulloch CE, Feldman HI, Go AS, Lash J, Bansal N, He J, Horwitz E, Ricardo AC, Shafi T, Sondheimer J, Townsend RR, Waikar SS, Hsu CY; Am J Kidney Dis. 2019 Nov 12:S0272-6386(19)30974-6. doi: 10.1053/j.ajkd.2019.08.011. Online ahead of print. Race and Mortality in CKD and Dialysis: Findings From the Chronic Renal Insufficiency Cohort (CRIC) Study. CRIC Study Investigators. Collaborators: Appel LJ, Kusek JW, Rao PS, Rahman M.

RATIONALE & OBJECTIVES: Few studies have investigated racial disparities in survival among dialysis patients in a manner that considers risk factors and mortality during the phase of kidney disease before maintenance dialysis. Our objective was to explore racial variations in survival among dialysis patients and relate them to racial differences in comorbid conditions and rates of death in the setting of kidney disease not yet requiring dialysis therapy.

STUDY DESIGN: Retrospective cohort study.

SETTINGS & PARTICIPANTS: 3,288 black and white participants in the Chronic Renal Insufficiency Cohort (CRIC), none of whom were receiving dialysis at enrollment.

EXPOSURE: Race.

OUTCOME: Mortality.

ANALYTIC APPROACH: Cox proportional hazards regression was used to examine the association between race and mortality starting at: (1) time of dialysis initiation and (2) entry into the CRIC.

RESULTS: During 7.1 years of median follow-up, 678 CRIC participants started dialysis. Starting from the time of dialysis initiation, blacks had lower risk for death (unadjusted HR, 0.67; 95% CI, 0.51-0.87) compared with whites. Starting from baseline CRIC enrollment, the strength of the association between some risk factors and dialysis was notably stronger for whites than blacks. For example, the HR for dialysis onset in the presence (vs absence) of heart failure at CRIC enrollment was 1.30 (95% CI, 1.01-1.68) for blacks versus 2.78 (95% CI, 1.90-4.50) for whites, suggesting differential severity of these risk factors by race. When we included deaths occurring both before and after dialysis, risk for death was higher among blacks (vs whites) starting from CRIC enrollment (HR, 1.41; 95% CI, 1.22-1.64), but this finding was attenuated in adjusted models (HR, 1.08; 95% CI, 0.91-1.28).

LIMITATIONS: Residual confounding.

CONCLUSIONS: The apparent survival advantage among blacks over whites treated with dialysis may be attributed to selected transition of a subset of whites with more severe comorbid conditions onto dialysis.

[28] Am J Nephrol. 2019;49(3):241-253. doi: 10.1159/000497446. Epub 2019 Feb 28.

Temporal Trends in Incident Mortality in Dialysis Patients: Focus on Sex and Racial Disparities.

Shah S, Leonard AC, Meganathan K, Christianson AL, Thakar CV.

BACKGROUND: Racial minorities and women constitute substantial portions of the incident and prevalent end-stage renal disease (ESRD) population in the United States. Although ESRD is characterized by high mortality, temporal trends, and race and sex differences in mortality have not been studied. METHODS: We evaluated 944,650 adult patients who initiated dialysis between January 1, 2005 and December 31, 2014, using the United States Renal Data System, for sex-related and race-related trends in mortality. Logistic regression models adjusted for pre-dialysis health status were used to examine associations among the predictors' sex, race, and year of incident dialysis, and the outcome all-cause mortality at 1-year post ESRD. RESULTS: The mean age was 65 ± 14 years. The 1-year crude mortality rates in incident ESRD patients decreased by 28% from 2004 to 2015. Risk-adjusted 1-year mortality decreased by 3% for each later year of incident ESRD ($p < 0.001$). In general, from 2005 to 2014, mortality rates decreased across both sexes, and all races. White patients experienced the lowest reduction in adjusted 1-year mortality rates (16%). While women experienced a survival advantage over men in 2005, by 2014 it was reversed to survival advantage for men. Combining all years, the adjusted risk of dying at 1-year after initiating dialysis was lower in women than men (OR 0.98; 95% CI 0.97-0.99), and as compared to whites, was lower in blacks (OR 0.73; 95% CI -0.72-0.74), Hispanics (OR 0.64; 95% CI 0.63-0.65), Asians (OR 0.55; 95% CI 0.53-0.56), and Native Americans (OR 0.67; 95% CI 0.63-0.71).

CONCLUSION: The 1-year mortality rates among patients with ESRD have decreased steadily during a recent 10-year period across both men and women, and in all 5 races. Women have only a 2% lower risk of dying at 1-year after dialysis initiation than men. White patients had higher mortality as compared to other races. Our results suggest the need for sex, and race-specific treatment strategies in ESRD care.

[29] Bowman B, Zheng S, Yang A, Schiller B, Morfín JA, Seek M, Lockridge RS.

Am J Kidney Dis. 2018 Aug;72(2):278-283. doi: 10.1053/j.ajkd.2018.01.035. Epub 2018 Mar 3.

Improving Incident ESRD Care Via a Transitional Care Unit.

Dialysis care in the United States continues to move toward an emphasis on continuous quality improvement and performance benchmarking. Government- and industry-sponsored programs have evolved to assess and incentivize outcomes for many components of end-stage renal disease care. One aspect that remains largely unaddressed at a systemic level is the high-risk transition period from chronic kidney disease and acute kidney injury to permanent dialysis dependence. Incident dialysis patients experience disproportionately high mortality and hospitalization rates coupled with high costs. This article reviews the clinical case for a special emphasis on this transition period, reviews published literature regarding prior transitional care programs, and proposes a novel iteration of the first 30 days of dialysis care: the transitional care unit (TCU). The goal of a TCU is to improve awareness of all aspects of renal replacement therapy, including modalities, access, transplantation options, and nutritional and psychosocial aspects of the disease. This enables patients to make truly informed decisions regarding their care. The TCU model is open to all patients, including incident patients with end-stage renal disease, those for whom peritoneal dialysis is failing, or those with failing transplants. This model may be especially beneficial to those who are deemed inadequately prepared or "crash start" patients.

[30] Li T, Wilcox CS, Lipkowitz MS, Gordon-Cappitelli J, Dragoi S.

Am J Nephrol. 2019;50(6):411-421. doi: 10.1159/000503805. Epub 2019 Oct 18.

Rationale and Strategies for Preserving Residual Kidney Function in Dialysis Patients.

BACKGROUND: Residual kidney function (RKF) conveys a survival benefit among dialysis patients, but the mechanism remains unclear. Improved volume control, clearance of protein-bound and middle molecules, reduced inflammation and preserved erythropoietin and vitamin D production are among the proposed mechanisms. Preservation of RKF requires techniques to measure it accurately to be able to uncover factors that accelerate its loss and interventions that preserve it and ultimately to individualize therapy. The average of renal creatinine and urea clearance provides a superior estimate of RKF in dialysis patients, when compared with daily urine volume. However, both involve the difficult task of obtaining an accurate 24-h urine sample. SUMMARY: In this article, we first review the definition and measurement of RKF, including newly proposed markers such as serum levels of beta2-microglobulin, cystatin C and beta-trace protein. We then discuss the predictors of RKF loss in new dialysis patients. We review several strategies to preserve RKF such as renin-angiotensin-aldosterone system blockade, incremental dialysis, use of biocompatible membranes and ultrapure dialysate in hemodialysis (HD) patients, and use of biocompatible solutions in peritoneal dialysis (PD) patients. Despite their generally

adverse effects on renal function, aminoglycoside antibiotics have not been shown to have adverse effects on RKF in well-hydrated patients with end-stage renal disease (ESRD). Presently, the roles of better blood pressure control, diuretic usage, diet, and dialysis modality on RKF remain to be clearly established. Key Messages: RKF is an important and favorable prognostic indicator of reduced morbidity, mortality, and higher quality of life in both PD an HD patients. Further investigation is warranted to uncover factors that protect or impair RKF. This should lead to improved quality of life and prolonged lifespan in patients with ESRD and cost-reduction through patient centeredness, individualized therapy, and precision medicine approaches.

[31] Hou Y, Li X, Sun L, Qu Z, Jiang L, Du Y. Clin Chim Acta. 2017 Nov;474:108-113. doi: 10.1016/j.cca.2017.09.005. Epub 2017 Sep 10. Phosphorus and mortality risk in end-stage renal disease: A meta-analysis.

BACKGROUND: Studies on the association of abnormal serum phosphorus level with all-cause mortality in patients with end-stage renal disease (ESRD) have yielded inconsistent results.

OBJECTIVE: To evaluate the association of abnormal serum phosphorus level with all-cause mortality in patients with ESRD requiring dialysis by conducting a meta-analysis.

METHODS: Pubmed and Embase databases were searched through March 2017 to identify all observational studies that assessed the association between abnormal serum phosphorus level and all-cause mortality risk in patients with ESRD requiring dialysis. Pooled hazard risk (HR) with 95% confidence interval (CI) was calculated for the highest versus referent phosphorus category and lower versus referent phosphorus category, separately.

RESULTS: Nine cohort studies were eligible for analysis. During 12 to 97.6months follow-up duration, 24,463 death events occurred among 1,992,869 ESRD patients. Meta-analysis showed that the pooled HR of all-cause mortality was 1.16 (95% CI 1.06-1.28) for the lower versus referent serum phosphorus category. Similarly, patients with highest serum phosphorus levels were associated with an increased risk of all-cause mortality (HR 1.39; 95% CI 1.31-1.47) compared with those in the referent phosphorus category. Subgroup analyses revealed that the effect of phosphorus on the all-cause mortality risk appeared to be stronger within 2years follow-up.

CONCLUSIONS: Both very high and very low values of phosphorus are independently associated with an increased risk for all-cause mortality in ESRD patients requiring dialysis. This meta-analysis highlighted a non-linear association of serum phosphorus with all-cause mortality among dialysis-dependent ESRD patients.

[32] Gilbertson DT, Rothman KJ, Chertow GM, Bradbury BD, Brookhart MA, Liu J, Winkelmayer WC, Stürmer T, Monda KL, Herzog CA, Ashfaq A, Collins AJ, Wetmore JB.

J Am Soc Nephrol. 2019 Feb;30(2):346-353. doi: 10.1681/ASN.2018060581. Epub 2019 Jan 24.

Excess Deaths Attributable to Influenza-Like Illness in the ESRD Population.

BACKGROUND: Morbidity and mortality vary seasonally. Timing and severity of influenza seasons contribute to those patterns, especially among vulnerable populations such as patients with ESRD. However, the extent to which influenza-like illness (ILI), a syndrome comprising a range of potentially serious respiratory tract infections, contributes to mortality in patients with ESRD has not been quantified.

METHODS: We used data from the Centers for Disease Control and Prevention (CDC) Outpatient Influenza-like Illness Surveillance Network and Centers for Medicare and Medicaid Services ESRD death data from 2000 to 2013. After addressing the increasing trend in deaths due to the growing prevalent ESRD population, we calculated quarterly relative mortality compared with average third-quarter (summer) death counts. We used linear regression models to assess the relationship between ILI data and mortality, separately for quarters 4 and 1 for each influenza season, and model parameter estimates to predict seasonal mortality counts and calculate excess ILI-associated deaths.

RESULTS: An estimated 1% absolute increase in quarterly ILI was associated with a 1.5% increase in relative mortality for quarter 4 and a 2.0% increase for quarter 1. The average number of annual deaths potentially attributable to ILI was substantial, about 1100 deaths per year.

CONCLUSIONS: We found an association between community ILI activity and seasonal variation in all-cause mortality in patients with ESRD, with ILI likely contributing to >1000 deaths annually. Surveillance efforts, such as timely reporting to the CDC of ILI activity within dialysis units during influenza season, may help focus attention on high-risk periods for this vulnerable population.

[33] Swaminathan S, Mor V, Mehrotra R, Trivedi AN. Am J Kidney Dis. 2017 Jul;70(1):69-75. doi: 10.1053/j.ajkd.2016.11.017. Epub 2017 Feb 21. Initial Session Duration and Mortality Among Incident Hemodialysis Patients.

BACKGROUND: The association of dialysis session duration with mortality in patients undergoing maintenance hemodialysis is unclear. We compared mortality rates of patients treated in dialysis facilities that used initial session durations of either ≥ 4 versus 3 hours for all incident patients.

STUDY DESIGN: Retrospective cohort study.

SETTINGS & PARTICIPANTS: Patients with end-stage renal disease beginning maintenance hemodialysis therapy in January 2006 to December 2010 and followed up through December 2012, including 39,172 patients in 852 facilities who initiated treatment for ≥ 4 hours and 47,721 patients in 631 facilities who initiated treatment for 3 hours.

PREDICTOR: Initial session duration of ≥ 4 hours versus 3 hours.

OUTCOME: 2- and 1-year mortality rates.

RESULTS: Total numbers of deaths observed within 2 years after initiating dialysis therapy were 8,945 in the ≥ 4-hour group and 15,624 in the 3-hour group. The corresponding numbers of deaths observed

within 1 year were 5,492 and 10,372, respectively. The 2-year adjusted HR in the ≥ 4-hour versus 3-hour group was 0.79 (95% CI, 0.73-0.86). The corresponding 1-year sdjusted HR was 0.77 (95% CI, 0.70-0.84). Results were robust when analyses were restricted to specific subgroups of patients classified by age, sex, race, and select clinical characteristics.

LIMITATIONS: We did not observe hemodialysis duration in sessions subsequent to initiation. We only included patients treated in facilities with uniform session length (at initiation) for all their patients. Furthermore, we lacked information for dialysis dosage and patients' baseline residual kidney function.

CONCLUSIONS: Patients in facilities routinely initiating hemodialysis therapy for ≥ 4 hours may have substantially lower mortality as compared with patients in facilities initiating for only 3 hours of treatment.

[34] Schold JD, Flechner SM(, Poggio ED, Augustine JJ, Goldfarb DA, Sedor JR, Buccini LD .Am J Kidney Dis. 2018 Jul;72(1):19-29. doi: 10.1053/j.ajkd.2017.12.014. Epub 2018 Mar 7. Residential Area Life Expectancy: Association With Outcomes and Processes of

Care for Patients With ESRD in the United States. Comment in Am J Kidney Dis. 2018 Jul;72(1):4-6.

BACKGROUND: The effects of underlying noncodified risks are unclear on the prognosis of patients with end-stage renal disease (ESRD). We aimed to evaluate the association of residential area life expectancy with outcomes and processes of care for patients with ESRD in the United States.

STUDY DESIGN: Retrospective cohort study.

SETTING & PARTICIPANTS: Adult patients with incident ESRD between 2006 and 2013 recorded in the US Renal Data System (n=606,046).

PREDICTOR: The primary exposure was life expectancy in the patient's residential county estimated by the Institute for Health Metrics and Evaluation.

OUTCOMES: Death, placement on the kidney transplant wait list, living and deceased donor kidney transplantation, and posttransplantation graft loss.

RESULTS: Median life expectancies of patients' residences were 75.6 (males) and 80.4 years (females). Compared to the highest life expectancy quintile and adjusted for demographic factors, disease cause, and multiple comorbid conditions, the lowest quintile had adjusted HRs for mortality of 1.20 (95% CI,

1.18-1.22); placement onto the waiting list, 0.68 (95% CI, 0.67-0.70); living donor transplantation, 0.53 (95% CI, 0.51-0.56); posttransplantation graft loss, 1.35 (95% CI, 1.27-1.43); and posttransplantation mortality, 1.29 (95% CI, 1.19-1.39). Patients living in areas with lower life expectancy were less likely

to be informed about transplantation, be under the care of a nephrologist, or receive an arteriovenous fistula as the initial dialysis access. Results remained consistent with additional adjustment for zip code-level median income, population size, and urban-rural locality.

LIMITATIONS: Potential residual confounding and attribution of effects to individuals based on residential area-level data.

CONCLUSIONS: Residential area life expectancy, a proxy for socioeconomic, environmental, genetic, and behavioral factors, was independently associated with mortality and process-of-care measures for patients with ESRD. These results emphasize the underlying effect on health outcomes of the environment in which patients live, independent of patient-level factors. These findings may have implications for provider assessments.

[35] BMC Nephrol. 2019 Jul 29;20(1):285. doi: 10.1186/s12882-019-1473-0. Long-term outcomes among Medicare patients readmitted in the first year of hemodialysis: a retrospective cohort study.

Ross KH, Jaar BG, Lea JP, Masud T, Patzer RE, Plantinga LC.

BACKGROUND: Readmission within 30 days of hospital discharge is common and costly among end-stage renal disease (ESRD) patients. Little is known about long-term outcomes after readmission. We estimated the association between hospital admissions and readmissions in the first year of dialysis and outcomes in the second year.

METHODS: Data on incident dialysis patients with Medicare coverage were obtained from the United States Renal Data System (USRDS). Readmission patterns were summarized as no admissions in the first year of dialysis (Admit-), at least one admission but no readmissions within 30 days (Admit+/Readmit-), and admissions with at least one readmission within 30 days (Admit+/Readmit+).We used Cox proportional hazards models to estimate the association between readmission pattern and mortality, hospitalization, and kidney transplantation, accounting for demographic and clinical covariates.

RESULTS: Among the 128,593 Medicare ESRD patients included in the study, 18.5% were Admit+/Readmit+, 30.5% were Admit+/Readmit-, and 51.0% were Admit-. Readmit+/Admit+ patients had substantially higher long-term risk of mortality (HR = 3.32 (95% CI, 3.21-3.44)), hospitalization (HR = 4.46 (95% CI, 4.36-4.56)), and lower likelihood of kidney transplantation (HR = 0.52 (95% CI, 0.44-0.62)) compared to Admit- patients; these associations were stronger than those among Admit+/Readmit- patients.

CONCLUSIONS: Patients with readmissions in the first year of dialysis were at substantially higher risk of poor outcomes than either patients who had no admissions or patients who had hospital admissions but no readmissions. Identifying strategies to both prevent readmission and mitigate risk among patients who had a readmission may improve outcomes among this substantial, high-risk group of ESRD patients.

[36] Clin Nephrol. 2016 Nov;86 (2016)(11):262-269. doi: 10.5414/CN108816.

Data completeness as an unmeasured confounder in dialysis facility performance comparison with 1-year follow-up. Liu J, Krishnan M, Zhou J, Nieman KM, Peng Y, Gilbertson DT.

Aims: Standardized mortality and hospitalization ratios (SMRs, SHRs) are used to measure dialysis facility performance in the US, with adjustment for demographics and comorbid conditions derived from the end-stage renal disease (ESRD) Medical Evidence (ME) Report. Sensitivities are low for ME-based comorbidity, and levels of under-reporting may differ among facilities. We aimed to assess the effect of data inaccuracy on performance comparison.

METHODS: Using the United States Renal Data System ESRD database, we included patients who initiated hemodialysis July 1 - December 31 in each of the years 2006 - 2010, had Medicare as primary payer, were aged ≥ 66 years, and had no prior transplant. Patients were followed from dialysis initiation to the earliest of death, transplant, modality change, or 1 year. SMRs and SHRs were calculated for for-profit/non-profit and rural/urban facilities for ME-based and claims-based comorbidity, separately. Cox models were used for expected number of deaths and piecewise Poison models for expected number of hospitalizations. Comorbidity agreement was measured by κ-statistic. Testing of differences between ME-based and claims-based SMRs/SHRs was performed by bootstrap.

RESULTS: In all, 73,950 incident hemodialysis patients were included. κ-values for comorbidity agreement were low, < 0.5, except for diabetes (0.77). Percentages of claims-based comorbidity were similar for for-profit and non-profit facilities; ME-based comorbidity was lower for for-profit facilities. Differences between ME-based and claims-based SMRs/SHRs were statistically

significant. Compared with ME-based SMRs/SHRs, claims-based ratios decreased 0.9/0.6% for for-profit and 1/0.7% for urban facilities and increased 3.4/2.8% for non-profit and 5.9/4.1% for rural facilities.

CONCLUSIONS: Comorbidity data source may affect performance evaluation. The impact is larger for smaller groups.

[37] Am J Kidney Dis. 2017 Mar;69(3):367-379. doi: 10.1053/j.ajkd.2016.08.030. Epub

2016 Nov 17. Interdialytic Weight Gain: Trends, Predictors, and Associated Outcomes in the

International Dialysis Outcomes and Practice Patterns Study (DOPPS).

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.

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.

[38] Am J Kidney Dis. 2017 Jul;70(1):21-29. doi: 10.1053/j.ajkd.2016.10.024. Epub

2017 Jan 19. Serum Potassium and Short-term Clinical Outcomes Among Hemodialysis Patients:

Impact of the Long Interdialytic Interval. Brunelli SM, Du Mond C, Oestreicher N, Rakov V, Spiegel DM.

Comment in Am J Kidney Dis. 2017 Jul;70(1):4-7.

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.

[39] 18. Clin J Am Soc Nephrol. 2019 Feb 7;14(2):250-260. doi: 10.2215/CJN.08580718. Epub

2019 Jan 31. Fruit and Vegetable Intake and Mortality in Adults undergoing Maintenance

Hemodialysis. Saglimbene VM, Wong G, Ruospo M, Palmer SC, Garcia-Larsen

V, Natale P, Teixeira-Pinto A, Campbell KL, Carrero JJ, Stenvinkel P, Gargano L, Murgo AM, Johnson DW, Tonelli M, Gelfman R, Celia E, Ecder T, Bernat AG, Del Castillo D, Timofte D, Török M, Bednarek-Skublewska A, Duława J, Stroumza P, Hoischen S, Hansis M, Fabricius E, Felaco P, Wollheim C, Hegbrant J, Craig JC, Strippoli GFM.

BACKGROUND AND OBJECTIVES: Higher fruit and vegetable intake is associated with lower cardiovascular and all-cause mortality in the general population. It is unclear whether this association occurs in patients on hemodialysis, in whom high fruit and vegetable intake is generally discouraged because of a potential risk of hyperkalemia. We aimed to evaluate the association between fruit and vegetable intake and mortality in hemodialysis.

DESIGN, SETTING, PARTICIPANTS, & MEASUREMENTS: Fruit and vegetable intake was ascertained by the Global Allergy and Asthma European Network food frequency questionnaire within the Dietary Intake, Death and Hospitalization in Adults with ESKD Treated with Hemodialysis study, a multinational cohort study of 9757 adults on hemodialysis, of whom 8078 (83%) had analyzable dietary data. Adjusted Cox regression analyses clustered by country were conducted to evaluate the association between tertiles of fruit and vegetable intake with all-cause, cardiovascular, and noncardiovascular mortality. Estimates were calculated as hazard ratios with 95% confidence intervals (95% CIs).

RESULTS: During a median follow up of 2.7 years (18,586 person-years), there were 2082 deaths (954 cardiovascular). The median (interquartile range) number of servings of fruit and vegetables was 8 (4-14) per week; only 4% of the study population consumed at least four servings per day as recommended in the general population. Compared with the lowest tertile of servings per week (0-5.5, median 2), the adjusted hazard ratios for the middle (5.6-10, median 8) and highest (>10, median 17) tertiles were 0.90 (95% CI, 0.81 to 1.00) and 0.80 (95% CI, 0.71 to 0.91) for all-cause mortality, 0.88 (95% CI, 0.76 to 1.02) and 0.77 (95% CI, 0.66 to 0.91) for noncardiovascular mortality and 0.95 (95% CI, 0.81 to 1.11) and 0.84 (95% CI, 0.70 to 1.00) for cardiovascular mortality, respectively.

CONCLUSIONS: Fruit and vegetable intake in the hemodialysis population is low and a higher consumption is associated with lower all-cause and noncardiovascular death.

3.1.5 Systematic Review of the Evidence (for intermediate outcome, process, or structure performance measures, include those that are instrument-based) – as applicable (NQF Evidence Attachment 1a.3)

N/A

3.1.6 Other Source of Evidence – as applicable (NQF Evidence Attachment 1a.4)

N/A

3.1.6.1 Briefly Synthesize the Evidence (NQF Evidence Attachment 1a.4.1)

N/A

3.1.6.2 Process Used to Identify the Evidence? (NQF Evidence Attachment 1a.4.2)

N/A

3.1.6.3 Citation(s) for the Evidence (NQF Evidence Attachment 1a.4.3)

N/A

3.2 Performance Gap – Opportunity for Improvement (NQF Measure evaluation criterion 1b)

3.2.1 Rationale (NQF Submission Form 1b.1.)

While mortality rates among ESRD patients on chronic dialysis have decreased in the US between 2001 to 2017 (USRDS 2019 Annual Data Report, Executive Summary), dialysis patients continue have higher mortality versus age-matched Medicare beneficiaries without ESRD (USRDS 2018 Annual Data Report, Chapter 5 Mortality). In addition, mortality among ESRD dialysis patients varies across dialysis facilities, even after adjustment for patients' characteristics. An adjusted facility-level mortality, which accounts

for differences in patients' characteristics, is one of several important health outcomes used by providers, health consumers, and insurers to evaluate the quality of care provided in dialysis facilities.

Reference: United States Renal Data System. 2019 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, 2019.

Reference: 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.

3.2.2 Performance Scores (NQF Submission Form 1b.2.) The average SMR remained stable across years and during the 2015 – 2018 period. The average SMR varied from 1.00 to 1.01. However, within any given year, there was a substantial gap in performance as SMR varied widely across facilities, with the 10th decile being as low as 0.55 and the 90th decile being as high as 1.50.

Distribution of SMRs of all facilities by year (2015-2018):

2015: Facilities = 5,793, Mean SMR = 1.01, Standard Deviation = 0.39, 10th =0.56, 25th = 0.75, 50th = .97, 75th = 1.22, 90th = 1.49

2016: Facilities = 5,977, Mean SMR = 1.01, Standard Deviation =0 .38, 10th = 0.57, 25th = 0.75, 50th = .97, 75th = 1.22, 90th = 1.51

2017: Facilities =6,223, Mean SMR = 1.00, Standard Deviation = 0.39, 10th = 0.55, 25th = 0.75, 50th = .97, 75th = 1.22, 90th = 1.50

2018: Facilities = 6,419, Mean SMR = 1.00, Standard Deviation = 0.39, 10th = 0.55, 25th =0.73, 50th = .95, 75th = 1.22, 90th = 1.48

Across the 4-year SMR (2015-2018): Facilities = 6,971, Mean SMR = 1.01, Standard Deviation = 0.28, 10th = 0.71, 25th = 0.83, 50th = .98, 75th = 1.15, 90th = 1.34

3.2.3 Summary of Data Indicating Opportunity (NQF Submission Form 1b.3.)

N/A

3.2.4 Disparities (NQF Submission Form 1b.4.)

Data from 2015-2018 show that black patients were at lower risk of mortality compared to white patients (HR = 0.75), as were Native American Asian/Pacific Islander patients, compared to patients of white race (HR = .89, 0.70). Hispanic and unknown ethnicity patients had lower risk of mortality (HR = 0.73 and 0.76, respectively) compared to non-Hispanic patients; and female patients had lower mortality risk than male patients (HR= 0.92). Further, patients unemployed at ESRD incidence have a

higher risk of mortality (HR 1.13) compared to those employed at ESRD incidence; dual eligible patients have a nominally lower risk of mortality (HR 0.99). Finally, Area Deprivation Index had no impact on mortality risk (HR 1.0002). More details can be seen in the section on risk adjustment and SDS/SES.

3.2.5 Provide summary of data if no or limited data (NQF Submission Form 1b.5.)

N/A

4. Scientific Acceptability (NQF Scientific Acceptability Tab)

4.1 Data Sample Description (NQF Testing Attachment 1.)

4.1.1 What Type of Data Were Used for Testing? (NQF Testing Attachment 1.1.)

Claims/Registry

4.1.2 Identify the Specific Dataset (NQF Testing Attachment 1.2.)

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.

4.1.3 What Are the Dates of the Data Used in Testing? (NQF Testing Attachment 1.3.)

2016 submission: Calendar years 2010 through 2013

2019 submission: January 2015- December 2018

4.1.4 What Levels of Analysis Were Tested? (NQF Testing Attachment 1.4.)

Hospital/Facility/Agency

4.1.5 How Many and Which Measured Entities Were Included in the Testing and Analysis? (NQF Testing Attachment 1.5.)

2016 Submission

For each year of the four years from 2010-2013, there were 5,004, 5,155, 5,279, and 5,409 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	461,495	64
2016	7,316	474,838	64
2017	7,590	486,818	64
2018	7,890	492,837	62

4.1.6 How Many and Which Patients Were Included in the Testing and Analysis? (NQF Testing Attachment 1.6.)

2016 Submission

For each year of the four years from 2010-2013, there were 373,002, 382,145, 390,893, and 397,804 patients, respectively.

2019 Submission

For each of the four years from 2015-2018 there were 461,495, 474,838, 486,818 and 492,837 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	31.2
Medicare primary + no Medicaid	38.9
HMO	20.9
Medicare secondary/Other	9.1
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

Patient Demographics	Percent
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	59.9
Black	31.8
Asian/Pacific Islander	5.1
Native American/Alaskan Native	1.1
Other/Unknown	2.1
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.

4.1.7 Sample Differences, if Applicable (NQF Testing Attachment 1.7.)

N/A

4.1.8 What Social Risk Factors Were Available and Analyzed? (NQF Testing Attachment 1.8.)

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.

4.2 Reliability Testing **(for reference only)** (NQF Testing Attachment 2a.2.) **Reliability testing** [10] demonstrates the measure data elements are repeatable, producing the same results a high proportion of the time when assessed in the same population in the same time period and/or that the measure

score is precise. For **instrument-based measures** (including PRO-PMs) **and composite performance measures**, reliability should be demonstrated for the computed performance score.

4.2.1 Level of Reliability Testing (NQF Testing Attachment 2a2.1.)

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

4.2.2 Method of Reliability Testing (NQF Testing Attachment 2a2.2.)

2011 Submission

To assess reliability, we assessed the degree to which the SMR was 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 SMR values was assessed across the years 2006, 2007, 2008 and 2009 based on the 5,280 dialysis centers for which an SMR is reported in the 2010 DFRs.

2016 Submission

The reliability of the Standardized Mortality Ratio (SMR) was assessed using data among 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 SMR, 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.

Suppose that there are N facilities with at least 3 expected deaths in the year. Let $T_1,\ldots,T_N$ be the SMR for these facilities. Within each facility, select at random and with replacement $B = 100$ bootstrap samples. 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 SMR_i and repeat the process 100 times. Thus, for the ith facility, we have bootstrapped SMRs of $T^*_{i1},\ldots,T^*_{i100}$. Let S_i^* be the sample variance of this bootstrap sample. From this it can be seen that

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

is a bootstrap estimate of the within-facility variance in the SMR, 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

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

where

$$\bar{T} = \Sigma\, n_i T_i / \Sigma\, n_i$$

is the weighted mean of the observed SMR and

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

is approximately the average facility size (number of patients per facility). 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

$$\text{IUR} = \sigma_b^2 / (\sigma_b^2 + \sigma_{t,w}^2$$

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

The SMR calculation only included facilities with at least 3 expected deaths for each year.

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 SMR 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.

4.2.3 Statistical Results from Reliability Testing (NQF Testing Attachment 2a2.3.)

2011 Submission

The correlation between SMR across adjacent years (2006 vs. 2007, 2007 vs 2008, and 2008 vs. 2009) ranged from 0.26 to 0.33, indicating that centers with large or small SMR tended to have larger or smaller SMR on the following year. These correlations were highly significant. Similarly, there was persistence in SMRs that were significant from year to year.

For example, there were 4.6% of facilities that had an SMR significantly greater than 1.0 in 2006 (18.3% did not have an SMR). Among those facilities, 30% were again significantly larger than 1.0 in 2007. Of the 3.1% of facilities that were significantly less than 1.0 in 2006, 18% were found to be significantly less than 1.0 in 2007. Among the 74% of facilities that had an SMR not significantly different from 1.0 in 2006, 87% remained in that category 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

Table 1: IUR for One-year SMR 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 Facilities	**0.32**	5004	**0.26**	5155	**0.30**	5279	**0.28**	5409
Small (<=45)	**0.07**	1137	**0.06**	1205	**0.03**	1241	**0.10**	1256

	2010		2011		2012		2013	
Medium (46–85)	0.19	1924	0.16	1967	0.17	2018	0.17	2132
Large (>=86)	0.48	1943	0.39	1983	0.47	2020	0.42	2022

Table 2: IUR for Four-year SMR Overall and by Facility Size, 2010-2013

Facility Size (Number of patients)	IUR	N
All Facilities	0.59	5935
Small (<=135)	0.30	1242
Medium (136–305)	0.45	2320
Large (>=306)	0.73	2373

2019 SUBMISSION

The overall IUR for the four-year SMR (2015-2018) is 0.5. The PIUR is 0.77. 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.

4.2.4 Interpretation (NQF Testing Attachment 2a2.4.)

2011 Submission

This was not a question on the 2011 Submission Form.

2016 Submission

Overall, we found that IURs for the one-year SMR have a range of 0.26-0.32 across the years 2010, 2011, 2012, and 2013, which indicates that about thirty percent of the variation in the one-year SMR can be attributed to the between-facility differences and about seventy percent to within-facility variation. This value of IUR indicates a relatively **low degree of reliability**. When stratified by facility size, we find that, as expected, larger facilities have greater IUR.

Reliability improved when four-year data were used. Overall, we found that IUR for the four-year SMR for 2010-2013 is 0.59 which indicates that about sixty percent of the variation in the four-year SMR can be attributed to the between-facility differences (signal) and about forty percent to within-facility variation (noise). This value of IUR indicates a **moderate 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 SMR is effective at detecting outlier facilities and statistically meaningful differences in performance scores across dialysis facilities.

4.3 Validity Testing **(for reference only)** (NQF Testing Attachment 2b1.) **Validity testing** [11] demonstrates that the measure data elements are correct and/or the measure score correctly reflects the quality of care provided, adequately identifying differences in quality. For **instrument-based measures (including PRO-PMs) and composite performance measures**, validity should be demonstrated for the computed performance score.

4.3.1 Level of Validity Testing (NQF Testing Attachment 2b1.1.)

☒ **Performance measure score**
☒ **Empirical validity testing**
☒ **Systematic assessment of face validity of performance measure score**

4.3.2 Method of Validity Testing (NQF Testing Attachment 2b1.2.)

2011 Submission

Adjusted mortality and fractions of patients achieving K/DOQI guidelines for urea reduction ratios (URRs; > or =65%) and hematocrit levels (> or =33%) were computed for 2,858 dialysis facilities from 1999 to 2002 using national data for patients with end-stage renal disease. Linear and Poisson regression were used to study the relationship between K/DOQI compliance and mortality and between changes in compliance and changes in mortality.

Measure validity is also demonstrated by the relationship of the Standardized Mortality Ratio to other quality of care indicators, including hemoglobin greater than 10 g/dL, urea reduction ratio >= 65%, percent of patients dialyzing with a fistula, and percent of patients dialyzing with a catheter.

2016 Submission

Measure validity is demonstrated by the relationship of the Standardized Mortality Ratio to other quality of care indicators, including the Standardized Hospitalization Ratio (SHR) – Admissions, the Standardized Readmission Ratio (SRR), the Standardized Transfusion Ratio (STrR), percent of patients dialyzing with a fistula, percent of patients dialyzing with a catheter, and percent of patients with Kt/V >=1.2. Spearman's rho is reported for all variables. Because the correlations were approximately the same for the four years 2010-2013, we are reporting only the 2013 correlations.

The measure is also maintained on face validity. It was reviewed by a TEP in 2006 for potential implementation on DFC. The general consensus was the SMR captured meaningful information on survival that DFC users could use to assess facility quality. 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.

2019 Submission

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

Negative Relationships

- Vascular Access: Standardized Fistula Rate (SFR) – We expect a negative association between SFR and SMR. 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 mortality. Higher rates of the facility level SFR will be negatively associated with mortality as measured by SMR.
- Kt/V ≥ 1.2: We expect a negative association between the facility percentage of patients with Kt/V>= 1.2 and SMR. 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 adverse outcomes. 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 mortality. Higher rates of the facility level percentage of patients with adequate dialysis (facility percentage Kt/V≥ 1.2) will be negatively associated with SMR.

Positive Relationships

- Vascular Access: Long-term catheter rate (catheter in use >=3 continuous months) – We expect a positive association between the long-term catheter rate and SMR. 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 be at higher risk of mortality. Higher long-term catheter rates will be positively associated with SMR.
- SHR: We expect a positive association between SHR and SMR. Patients who require acute medical care in the hospital 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.
- SRR: We expect a positive association between SRR and SMR. Both hospitalization and readmission are a reflection of hospital utilization and increased comorbidity burden. Additionally, patients readmitted after a recent discharge indicates they still require acute medical attention or experience other post-discharge complications placing them at higher risk for mortality.
- STrR: We expect a positive association between STrR and SMR. Patients with severe anemia may require hospitalization and blood transfusion, placing them at risk for other adverse events and potentially higher risk for mortality.

The measure is also maintained on face validity. It was reviewed by a TEP in 2006 for potential implementation on DFC. The general consensus was the SMR captured meaningful information on survival that DFC users could use to assess facility quality. 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.

4.3.3 Statistical Results from Validity Testing (NQF Testing Attachment 2b1.3.)

2011 Submission

In 2002, facilities in the lowest quintile of K/DOQI compliance for urea reduction ratio (URR) and hematocrit guidelines had 22% and 14% greater mortality rates (P < 0.0001) than facilities in the highest quintile, respectively. A 10-percentage point increase in fraction of patients with a URR of 65% or greater was associated with a 2.2% decrease in mortality (P = 0.0006), and a 10-percentage point increase in percentage of patients with a hematocrit of 33% or greater was associated with a 1.5% decrease in mortality (P = 0.003). Facilities in the highest tertiles of improvement for URR and hematocrit had a change in mortality rates that was 15% better than those observed for facilities in the lowest tertiles (P < 0.0001).

Please see the following publication for further details: Wolfe RA, Hulbert-Shearon TE, Ashby VB, Mahadevan S, Port FK. Improvements in dialysis patient mortality are associated with improvements in urea reduction ratio and hematocrit, 1999 to 2002. Am J Kidney Dis. 2005 Jan;45(1):127-35.

2016 Submission

SHR-Admissions: rho=0.20, p<.0001

SRR-Readmissions: rho=0.10, p<.0001

STrR: rho=0.21, p<.0001

AV Fistula: rho= -0.11, p<.0001

Catheter: rho=0.13, p<.0001

Hemodialysis patients with Kt/V>=1.2: rho= -0.04, p<.0001

2019 Submission

Table 3. Correlation between SMR and other Measures, 2018

Measure	Spearman's rho	p-value
SFR	-0.08	<0.0001
Kt/V >=1.2	-0.16	<0.0001
Long-term Catheter	0.07	<0.0001
SHR	0.15	<0.0001
SRR	0.08	<0.0001
STrR	0.16	<0.0001

4.3.4 Interpretation (NQF Testing Attachment 2b1.4.)

2011 Submission

This was not a question on the 2011 Submission Form.

2016 Submission

As expected, the SMR is positively correlated with the SHR-Admissions (rho=0.20, p<.0001), SRR-Readmissions (rho=0.10, p<.0001), and the STrR (rho=0.21, p<.0001); higher standardized mortality rates in facilities are associated with higher standardized hospitalization rates, higher standardized readmissions rates and higher standardized transfusion rates. The SMR is negatively correlated with percent of patients in the facility with AV Fistula (rho= -0.11, p<.0001); lower standardized mortality rates are associated with higher rates of AV Fistula use. On the other hand, the SMR is positively correlated with catheter use (rho=0.13, p<.0001), indicating that higher values of SMR are associated with increased use of catheters. The SMR is also found to be negatively correlated (rho= -0.04, p<.0001) with the percent of hemodialysis patients with Kt/V>=1.2, again in the direction expected. Lower SMRs are associated with a higher percentage of patients receiving adequate dialysis dose.

2019 Submission

SMR is correlated with each of the quality performance measures in the expected direction. All correlations are statistically significant. As expected, the SMR is positively correlated for each individual year with the SHR-Admissions, SRR-Readmissions, and the STrR. The SMR is negatively correlated with the percent of hemodialysis patients with Kt/V>=1.2, in the direction expected indicting lower SMRs are associated with a higher percentage of patients receiving adequate dialysis dose. The SMR is negatively correlated with the percentage of patients in the facility with an AV Fistula as measured by SFR indicating lower standardized mortality rates are associated with a higher standardized fistula rate. On the other hand, the SMR is positively correlated with long-term catheter rates indicating that higher values of SMR are associated with higher rates of long-term catheters.

4.4 Exclusions Analysis **(for reference only)** (NQF Testing Attachment 2b2.) **Exclusions** are supported by the clinical evidence and are of sufficient frequency to warrant inclusion in the specifications of the measure; [12]

4.4.1 Method of Testing Exclusions (NQF Testing Attachment 2b2.1.)
N/A

4.4.2 Statistical Results From Testing Exclusions (NQF Testing Attachment 2b2.2.)

N/A

4.4.3 Interpretation (NQF Testing Attachment 2b2.3.)

N/A

4.5 Risk Adjustment or Stratification for Outcome or Resource Use Measures **(for reference only)** (NQF Testing Attachment 2b3) **an evidence-based risk-adjustment strategy** (e.g., risk models, risk stratification) is specified; is based on patient factors (including clinical and social risk factors) that influence the measured outcome and are present at start of care; [14,15] and has demonstrated adequate discrimination and calibration

OR

rationale/data support no risk adjustment/ stratification.

4.5.1 Method of Controlling for Differences (NQF Testing Attachment 2b3.1.)

☒ **Statistical risk model with 146 risk factors**

4.5.2 Rationale Why Risk Adjustment Is Not Needed (NQF Testing Attachment 2b3.2.)

N/A

4.5.3 Conceptual, Clinical, and Statistical Methods (NQF Testing Attachment 2b3.3.a.)

2016 Submission

The methods for development of the risk factor models have been published and documented previously (Wolfe 1992; Wolfe 2001). The final risk adjustment is based on a Cox or relative risk model. In this model, covariates are taken to act multiplicatively on the death 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) and Kalbfleisch and Prentice (2002). All analyses are performed using SAS.

In the SMR, adjustment is made for patient age, sex, race, ethnicity, cause of ESRD, duration of ESRD, nursing home status, BMI at incidence, comorbidities at incidence, prevalent comorbidities, and calendar year. The SMR is also adjusted for state population death rates.

Below we discuss factors considered for inclusion in the statistical risk model, with emphasis on new factors considered since the last cycle of NQF maintenance endorsement in 2011. We present results and discussion supporting the selection of specific risk factors in the model.

Risk adjustment factors were selected for testing based on several considerations, specifically clinical criteria, expert input, factors identified in the literature as associated with mortality, and data availability. We began with a large set of patient characteristics, comorbidities (at ESRD incidence and prevalent), anthropometrics, and other characteristics. Facility characteristics were also considered. Risk factors were evaluated for appropriateness of the adjustment. For instance, it is important not to adjust for factors that reflect the results of treatment. Factors considered appropriate and supported in the literature were then investigated with statistical models, including interactions between sets of adjusters, to determine if they were empirically related to mortality. Risk factors were also evaluated for face validity as potential predictors of mortality. Finally, SDS/SES factors were evaluated based on

appropriateness (whether related to disparities in care), empirical association with the outcome, and support in published literature.

Consideration of prevalent comorbidities as risk adjusters, in addition to incident comorbidities, is in part a response to stakeholder interest to adjust for more current (prevalent) comorbidities to reflect the current health status of dialysis patients, and conditions associated with mortality. 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. 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.

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 comorbidity diagnoses (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

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 in the model results section.

Consideration of SES/SDS risk factors:

In addition to clinical factors, we evaluated patient and area-level SDS/SES factors as risk adjusters. These were in addition to the current SDS factors of race, ethnicity, and sex. Race and sex were included in the original SMR calculation and ethnicity was added to the model in 2005.

The relationships among individual SDS factors, socioeconomic disadvantage and mortality is well-established in the general population (Singh and Siahpush, 2006; Williams, 2006; Williams and Collins, 2001). Further, individual and market or area-level measures of deprivation have been shown to contribute independently to higher mortality (Smith et al., 1998).

Area-level income and residential segregation specifically have been shown to be associated with poorer outcomes, but particularly so for racial minorities, suggesting the interplay of patient-level (race) and area-level factors related to lower income, neighborhood poverty, segregation, levels of educational attainment, and unemployment levels that jointly influence key health outcomes in mortality and morbidity (Williams, 2006; Williams and Collins, 2001). For example, Williams (2006) explains that differences in health outcomes and mortality by race persist, even after accounting for levels of SES. This suggests the potential added effect of historical and institutional discrimination (e.g., segregation; restricted educational access; fewer health-related resources in poor neighborhoods; no insurance or Medicaid status) that have cumulatively over time led to reduced access to care. Residential segregation of blacks in the U.S., Williams and Collins argue, is a primary cause of SES differences that in turn have resulted in a high prevalence of chronic diseases and related differences in health care outcomes such as mortality (Williams and C Collins 2001, p 404-406).

The relationship between race and mortality, as well as both race and area-level SES factors and mortality in the dialysis population, is also well documented (e.g., Burrows et al, 2014; Crews et al , 2001; Eisenstein et al, 2009; Johns et al , 2014; Kucirka et al, 2010; Ricks et al, 2011; Kalbfleisch et al., 2015; Rodriguez et al, 2007; Kimmel et al, 2013; Streja et al, 2011; Yan et al., 2013; Yan et al, 2013). However, the direction of the relationship between race and mortality is inverted relative to the general population, with lower observed mortality in blacks on chronic dialysis compared to whites, although the relationship is mediated by sociodemographic and clinical factors (Norris et al., 2008; Powe, 2006; Cowie et al. 1994). For example, while black ESRD patients overall have been observed to have lower mortality compared to whites, some studies have shown this difference is attenuated or disappears once accounting for one or more area level SES factors (Eisenstein et al 2009; Johns et al 2014; Rodriguez et al 2007; Crews et al., 2011; Ricks et al., 2011; Streja et al 2011; Johns et al 2014; Yan 2013; Yan et al 2014).

Differences based on clinical factors and Hispanic ethnicity have also been observed to impact lower mortality (Streja et al 2011; Johns et al 2014; Yan 2013; Yan et al 2013; Ricks et al 2011). Taken together race and ethnicity are shown to be strongly associated with mortality but in different clinical pathways after accounting for specific clinical markers of health status. Race was included as an adjuster in the prior version of SMR because accounting for within-facility racial differences helps to clarify disparities in quality of healthcare provided to patients with ESRD (Kalbfleisch et al., 2015).

Females in the general population have lower mortality rates (CDC National Vital Statistics Reports, 2012) than males. Adjustment for sex allows for a fair comparison between dialysis facilities with patient populations that have a different mix of males and females.

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 mortality. For example, Curtin et al (AJKD 1996) found that measures of functional status were higher in patients that were employed.

Insurance status is also related to health outcomes but this has not been studied extensively within the dialysis population as it relates to mortality. However some evidence suggests a link between dual eligibles and hospital utilization (Wright et al., 2015).

In sum these studies suggest notable associations with mortality differences when taking into account patient level SDS factors (race, sex, ethnicity), and area level SES factors. Additionally, employment status and type of insurance coverage (specifically Medicare-Medicaid dual eligibility) suggest a proximate relationship to health outcomes that may have downstream impacts on mortality.

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 on 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 methods for development of the risk factor models have been published and documented previously (Wolfe 1992; Wolfe 2001). The final risk adjustment is based on a Cox or relative risk model. In this model, covariates are taken to act multiplicatively on the death 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) and Kalbfleisch and Prentice (2002). All analyses are performed using SAS.

The denominator of SMR for a facility is the expected number of deaths from the patient-records meeting the inclusion criteria, based on the number of days attributed to that facility (the assignment rule will be detailed later), if the facility conforms to the national norm. Specifically, the expectation is calculated using a two-stage model. At Stage 1, we fit a Cox model (Cox, 1972) stratified by facility and adjusted for patient age, race, ethnicity, sex, diabetes, duration of ESRD, nursing home status, patient comorbidities, calendar year, and body mass index (BMI) at incidence. This stratified model allows each facility to have a distinct baseline survival function while retaining the same regression coefficients of all the adjusters across all the facilities. Stratification by facility avoids estimating facility effects directly and also reduces computational burden. A linear predictor using the estimates of regression coefficients will be computed for each patient and will be used as the offset term in the Stage 2 modeling. At Stage 2, we fit an unstratified Cox model, which includes the offset term from Stage 1 model as well as the race-specific age-adjusted state population death rates. The baseline hazard or survival function of this model has national norm interpretations. With the fitted model at Stage 2, we compute the expected probability of death for each patient based on the aforementioned adjusters and the number of days assigned to a facility. The denominator of SMR for a facility is then the summation of expected probabilities of death from all the patients assigned to that facility.

The patient characteristics included in the stage 1 model as covariates are:

- Age: Age is included as a piecewise continuous variable with different coefficients based on whether the patient is 0-13 years old, 14-60 years old, or 61+ years old.
- Sex

- Race: White, Black, Asian/PI, Native American or other
- Ethnicity: Hispanic, non-Hispanic or unknown
- Diabetes as cause of ESRD
- Duration of ESRD:
    - Less than one year
    - 1-2 years
    - 2-3 years
    - 3+ years
- 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 other than as primary 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 Medicare covered months in prior calendar year
- Calendar year

Beside main effects, two-way interaction terms between age, race, ethnicity, sex, duration of ESRD and diabetes as cause of ESRD are also included:

- Age and Race: Black
- Ethnicity and Race: Non-White
- Diabetes as cause of ESRD and Race
- Diabetes as cause of ESRD and Duration of ESRD
- Duration of ESRD: less than or equal to 1 year and Race
- Sex and Race: Black

Below we discuss how factors were considered for inclusion in the statistical risk model.

Risk adjustment factors were selected for testing based on several considerations, specifically clinical criteria, expert input, factors identified in the literature as associated with mortality, and data availability. We began with a large set of patient demographics, comorbidities (at ESRD incidence and prevalent), anthropometrics, and other characteristics. Facility characteristics were also considered. Risk factors were evaluated for appropriateness of the adjustment. For instance, it is important not to adjust for factors that reflect the results of treatment. Factors considered appropriate and supported in the literature were then investigated with statistical models, including interactions between sets of adjusters, to determine if they were empirically related to mortality. Risk factors were also evaluated for face validity as potential predictors of mortality.

Consideration of prevalent comorbidities as risk adjusters, in addition to incident comorbidities, is in part a response to stakeholder interest to adjust for more current (prevalent) comorbidities to reflect the current health status of dialysis patients, and conditions associated with mortality. CMS contracted with UM-KECC to convene a 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-measures. Specific 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 individual ICD-9 diagnosis codes 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 SMR 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 SMR 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. A patient is considered to have a particular prevalent comorbid condition if one of the ICD-10 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.

For this submission we also considered inclusion of an indicator for Medicare Advantage time at risk during the previous calendar year, as in the SHR measure. However, this variable was not statistically

significant for SMR and the coefficient was very small therefore it was not included in the final SMR model.

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 support in published literature (see section 2b3.3b).

4.5.4 Conceptual Model of Impact of Social Risks (NQF Testing Attachment 2b3.3b.)

☒ **Published literature**

☒ **Internal data analysis**

In addition to clinical factors, we evaluated patient and area-level SDS/SES social risk factors as risk adjusters. These were in addition to the current inclusion of race, ethnicity, and sex included in the currently endorsed and implemented SMR as described in the 2016 submission.

The relationships among individual SDS factors, socioeconomic disadvantage and mortality is well-established in the general population (Singh and Siahpush, 2006; Williams, 2006; Williams and Collins, 2001). Further, individual and market or area-level measures of deprivation have been shown to contribute independently to higher mortality (Smith et al., 1998).

The relationship between race and mortality, Hispanic ethnicity and mortality, as well as both race and area-level SES factors and mortality in the dialysis population, is also well documented (e.g., Burrows et al, 2014; Crews et al , 2001; Eisenstein et al, 2009; Johns et al , 2014; Kucirka et al, 2010; Ricks et al, 2011; Kalbfleisch et al., 2015; Rodriguez et al, 2007; Kimmel et al, 2013; Streja et al, 2011; Yan et al., 2013; Yan et al, 2013). However, the direction of the relationship between race and mortality is inverted relative to the general population, with lower observed mortality in blacks on chronic dialysis compared to whites, although the relationship is mediated by sociodemographic and clinical factors (Norris et al., 2008; Powe, 2006; Cowie et al. 1994).

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.

References:

Burrows N, Cho P, Bullard KM, Narva A, and Eggers P. Survival on Dialysis Among American Indians and Alaska Natives With Diabetes in the United States, 1995–2010. American Journal of Public Health. Supplement 3, 2014, Vol 104, No. S3. S490.

CDC National Vital Statistics Reports, Vol. 61, No. 6, October 10, 2012, Table A

Cowie C, Port F, Rust K, Harris M: Differences In Survival Between Black And White Patients With Diabetic End-Stage Renal Disease. Diabetes Care 17: 681–687, 1994

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

Crews D, Sozio S, Liu Y, Coresh J, and Powe N. Inflammation and the Paradox of Racial Differences in Dialysis Survival. J Am Soc Nephrol 22: 2279–2286, 2011.

Curtin R, Oberley E, Sacksteder P, and Friedman A. Differences Between Employed and Nonemployed Dialysis Patients. AJKD Vol 27:4. (April) 1996. 533-540.

Eisenstein E, Sun J, Anstrom K, Stafford J, Szczech L, Muhlbaier L, Mark D. Do Income Level and Race Influence Survival in Patients Receiving Hemodialysis? The American Journal of Medicine (2009) 122, 170-180.

Johns T, Estrella M, Crews D, Appel L, Anderson C, Ephraim P, Cook C, and Boulware L. Neighborhood Socioeconomic Status, Race, and Mortality in Young Adult Dialysis Patients. Am Soc Nephrol 25: epub, 2014.

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

Kalbfleisch J, Wolfe R, Bell S, Sun R, Messana J, Shearon T, Ashby V, Padilla R, Zhang M, Turenne M, Pearson J, Dahlerus C, and Li Y. Risk Adjustment and the Assessment of Disparities in Dialysis Mortality Outcomes. J Am Soc Nephrol 26: 2641–2645, 2015

Kimmel P, Fwu CW, and Eggers P. Segregation, Income Disparities, and Survival in Hemodialysis Patients. JASN. February 2013 vol. 24 no. 2 293-301.

Kucirka L, Grams M, Lessler J, Hall E, James J, Massie A, Montgomery R, and Segev D. Age and Racial Disparities in Dialysis Survival. JAMA. 2011 August 10; 306(6): 620–626. doi:10.1001/jama.2011.1127

Norris K, Mehrotra R, Nissenson A. Racial Differences in Mortality and ESRD. American Journal of Kidney Diseases, Volume 52, Issue 2, August 2008, Pages 205–208.

Powe, NR. Reverse Race And Ethnic Disparities In Survival Increase With Severity Of Chronic Kidney Disease: What Does This Mean? Clin J Am Soc Nephrol 1: 905–906, 2006;

Ricks R, Molnar M, Kovesdy C, Kopple J, Norris K, Mehrotra R, Nissenson A, Arah O, Greenland S, and Kalantar-Zadeh K. Racial and Ethnic Differences in the Association of Body Mass Index and Survival in Maintenance Hemodialysis Patients. Am J Kidney Dis. 2011 October ; 58(4): 574–582.

Rodriguez R, Sen S, Mehta K, Moody-Ayers S, Bacchetti P, and O'Hare A. Geography Matters: Relationships among Urban Residential Segregation, Dialysis Facilities, and Patient Outcomes. Ann Intern Med. 2007;146:493-501.

Singh, G. Area Deprivation and Widening Inequalities In US Mortality, 1969–1998. Am J Public Health. 2003;93(7):1137–1143

University of Wisconsin School of Medicine Public Health. 2015 Area Deprivation Index v2.0. Downloaded from https://www.neighborhoodatlas.medicine.wisc.edu. Accessed 10/31/2018.

Singh G and Siahpush M. Widening Socioeconomic Inequalities In US Life Expectancy, 1980–2000. Int. J. Epidemiol. (August 2006) 35 (4): 969-979

Smith G, Hart C, Watt G, Hole D, Hawthorne V. Individual Social Class, Area-Based Deprivation, Cardiovascular Disease Risk Factors, And Mortality: the Renfrew and Paisley Study. J Epidemiol Community Health 1998; 52:399-405

Streja E, Kovesdy C, Molnar M, Norris K, Greenland S, Nissenson A, Kopple J, and Kalantar-Zadeh K. Role of Nutritional Status and Inflammation in Higher Survival of African American and Hispanic Hemodialysis Patients. Am J Kidney Dis. 2011 June ; 57(6): 883–893.

University of Wisconsin School of Medicine Public Health. 2013 Area Deprivation Index v1.5. Downloaded from https://www.neighborhoodatlas.medicine.wisc.edu/ October 31, 2018.

Williams D. "Race, Socioeconomic Status, and Health: The Added Effects of Racism and Discrimination. Annals of the New York Academy of Sciences. Volume 896, Issue 1, Article first published online: 6 February 2006.

Williams D, and Collins C, Racial Residential Segregation: A Fundamental Cause of Racial Disparities in Health. Public Health Reports / September–October 2001. Volume 116. 404-416.

Wolfe RA et al: New Dialysis Facility Mortality Statistics (Smrs) Adjust For More Patient Characteristics. J Am Soc Nephrol 2001; 12; A1802

Wolfe R et al. Using USRDS Generated Mortality Tables To Compare Local ESRD Mortality Rates To National Rates. Kidney Int 1992; 42: 991-96

Wright B, Potter A, and Trivedi A. Federally Qualified Health Center Use Among Dual Eligibles: Rates Of Hospitalizations And Emergency Department Visits Health Affairs, 34, no.7 (2015):1147-1155

Yan G, Norris K, Xin W, Ma J, Yu A, Greene T, Yu W, and Cheung A. Facility Size, Race and Ethnicity, and Mortality for In-Center Hemodialysis. J Am Soc Nephrol 24: 2062–2070, 2013. doi: 10.1681.

Yan G, Norris K, Yu A, Ma J, Greene T, Yu W, and Cheung A. The Relationship of Age, Race, and Ethnicity with Survival in Dialysis Patients. Clin J Am Soc Nephrol 8: 953–961, 2013. doi: 10.2215.

4.5.5 Statistical Results (NQF Testing Attachment 2b3.4a.)

2016 Submission

Analyses of Comorbidities and other Clinical Factors

Table 3a presents the SMR model coefficients. Of note, it shows the coefficients on the prevalent comorbidities that were recommended by the TEP as additional risk adjusters (i.e., in addition to the risk adjusters in the SMR model since the 2011 endorsement maintenance review).

Table 3a. Model Coefficients, Data Years 2010–2013

Covariate	Coefficient	p-value
Comorbidities at start of ESRD		
At least of the comorbidities listed below	0.15783	<.0001
Atherosclerotic heart disease	0.04559	<.0001
Other cardiac disease	0.06736	<.0001
Diabetes (all types including diabetic retinopathy)*	0.01596	0.0389
Congestive heart failure	0.12221	<.0001
Inability to ambulate	0.14953	<.0001
Chronic obstructive pulmonary disease	0.07399	<.0001
Inability to transfer	0.11727	<.0001
Malignant neoplasm, cancer	0.10791	<.0001
Peripheral vascular disease	0.05252	<.0001
Cerebrovascular disease, CVA, TIA	0.01484	0.0311
Tobacco use (current smoker)	0.10783	<.0001
Alcohol dependence	0.03135	0.0989
Drug dependence	0.07436	0.0008
No Medical Evidence (CMS-2728) Form	0.0115	0.7696
Cause of ESRD		
Diabetes	0.14834	<.0001
Missing	-0.02574	0.2855
Sex: Female	-0.07704	<.0001
Age		
Age (continuous)	-0.05786	0.0003

Covariate	Coefficient	p-value
Age spline at 14	0.08753	<.0001
Age spline at 60	0.00651	<.0001
Race: black X age interaction		
Age (continuous)	-0.0371	0.1983
Age spline at 14	0.03412	0.2384
Age spline at 60	0.0009396	0.4437
Patient in nursing home	0.31026	<.0001
Incident BMI		
Log of BMI (continuous)	-0.48904	<.0001
Log of BMI spline at 35	0.57016	<.0001
BMI Missing	0.14771	<.0001
Race		
White	Reference	-
Black	0.31856	0.4275
Asian/PI	-0.33283	<.0001
Native American	-0.12939	0.0015
Other	-0.25062	<.0001
Time on ESRD		
< 1 year	-0.18009	<.0001
1 to 2 years	-0.21764	<.0001
2 to 3 years	-0.17079	<.0001
3+ years	Reference	-
Calendar year		
2010	0.1289	<.0001
2011	0.10334	<.0001
2012	0.00509	0.3735
2013	Reference	-
Ethnicity		
Hispanic	-0.31125	<.0001
Non-Hispanic ethnicity	Reference	
Unknown ethnicity	0.09259	0.0082
Ethnicity X race: nonwhite interaction		
Hispanic ethnicity	0.30208	<.0001
Unknown ethnicity	0.12773	0.0004
Race X diabetes as cause of ESRD interaction		
Asian/PI	0.04491	0.0405
Black	-0.08505	<.0001
Native American	-0.00639	0.8865
Other	0.10269	0.0266
Time with ESRD X diabetes as cause of ESRD interaction		
< 1 year	-0.20115	<.0001
1 to 2 years	-0.11321	<.0001
2 to 3 years	-0.04516	0.0004
3+ years	Reference	-
Time on ESRD: < 1 year X race interaction		
Asian/PI	-0.13672	<.0001
Black	0.03974	0.0003
Native American	-0.10883	0.0344
Other	0.26902	<.0001
Time on ESRD: < 1 year X sex: female interaction	0.00915	0.3193

Covariate	Coefficient	p-value
Sex: female X cause of ESRD: diabetes interaction	-0.00839	0.3009
Race: black X sex: female interaction	0.06686	<.0001

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

Table 3b. Prevalent Comorbidity Coefficients, Data Years 2010–2013

ICD-9 Description	ICD-9 Code	Coefficient	P-value
Sarcoidosis	135	0.0498	0.1881
Malign neopl prostate	185	-0.06496	<.0001
Malign neopl thyroid	193	-0.24613	<.0001
Oth severe malnutrition	262	0.17484	<.0001
Chr airway obstruct NEC	496	0.16266	<.0001
Postinflam pulm fibrosis	515	0.15118	<.0001
Malignant neopl rectum	1541	0.30273	<.0001
Mal neo liver, primary	1550	0.36764	<.0001
Mal neo upper lobe lung	1623	0.27901	<.0001
Mal neo bronch/lung NOS	1629	0.41213	<.0001
Malig neo bladder NOS	1889	0.19631	<.0001
Malig neopl kidney	1890	-0.04592	0.0198
Secondary malig neo lung	1970	0.5234	<.0001
Second malig neo liver	1977	0.90921	<.0001
Secondary malig neo bone	1985	0.71735	<.0001
Malignant neoplasm NOS	1991	0.35314	<.0001
Protein-cal malnutr NOS	2639	0.19068	<.0001
Dis urea cycle metabol	2706	-0.01549	0.7273
Senile dementia uncomp	2900	0.07334	<.0001
Drug withdrawal	2920	0.13901	0.0014
Mental disor NEC oth dis	2948	0.16473	<.0001
Cereb degeneration NOS	3319	0.10725	<.0001
Aut neuropthy in oth dis	3371	0.02175	0.1983
Grand mal status	3453	-0.00454	0.8984
Anoxic brain damage	3481	0.2873	<.0001
Cerebral edema	3485	0.21974	<.0001
Idio periph neurpthy NOS	3569	0.03128	0.0003
Neuropathy in diabetes	3572	0.0258	0.0042
Intermed coronary synd	4111	0.05768	<.0001
Angina pectoris NEC/NOS	4139	0.00621	0.5314

ICD-9 Description	ICD-9 Code	Coefficient	P-value
Prim pulm hypertension	4160	0.05884	0.0002
Chr pulmon heart dis NEC	4168	0.1898	<.0001
Prim cardiomyopathy NEC	4254	0.23084	<.0001
Cardiomyopath in oth dis	4258	0.04292	0.0329
Atriovent block complete	4260	0.15129	<.0001
Parox ventric tachycard	4271	0.18283	<.0001
Parox tachycardia NOS	4272	0.07202	0.0747
Subdural hemorrhage	4321	0.13039	<.0001
Aortic atherosclerosis	4400	0.03595	0.0233
Lower extremity aneurysm	4423	0.02375	0.4642
Periph vascular dis NOS	4439	0.16444	<.0001
Stricture of artery	4471	-0.02833	0.0635
Oth inf vena cava thromb	4532	0.30687	<.0001
Emphysema NEC	4928	0.07809	<.0001
Bronchiectas w/o ac exac	4940	0.03515	0.3221
Food/vomit pneumonitis	5070	0.1607	<.0001
Lung involv in oth dis	5178	0.15956	0.0088
Regional enteritis NOS	5559	0.12126	0.0002
Ulceratve colitis unspcf	5569	0.02044	0.5561
Chr vasc insuff intest	5571	0.13302	<.0001
Paralytic ileus	5601	-0.01047	0.5007
Intestinal obstruct NOS	5609	0.08494	<.0001
Alcohol cirrhosis liver	5712	0.15572	<.0001
Cirrhosis of liver NOS	5715	0.41697	<.0001
Hepatic encephalopathy	5722	0.31225	<.0001
Portal hypertension	5723	0.22903	<.0001
Oth sequela, chr liv dis	5728	0.2376	<.0001
Chronic pancreatitis	5771	0.17966	<.0001
Chronic skin ulcer NEC	7078	0.14188	<.0001
Syst lupus erythematosus	7100	0.19554	<.0001
Systemic sclerosis	7101	0.39484	<.0001
Rheumatoid arthritis	7140	0.0896	<.0001
Inflamm polyarthrop NOS	7149	-0.02268	0.6699
Sacroiliitis NEC	7202	0.04558	0.2878
Gangrene	7854	0.17237	<.0001
Cachexia	7994	0.33328	<.0001
Fracture of pubis-closed	8082	0.11422	0.0001
Pelvic fracture NOS-clos	8088	0.05103	0.1367
Fx neck of femur NOS-cl	8208	0.04397	0.0051
Amput below knee, unilat	8970	-0.09002	<.0001

ICD-9 Description	ICD-9 Code	Coefficient	P-value
Amputat bk, unilat-compl	8971	-0.01234	0.7926
Amput above knee, unilat	8972	-0.11732	<.0001
Amputat leg, unilat NOS	8974	-0.08497	0.064
Candidal esophagitis	11284	0.21728	<.0001
Oth lymp unsp xtrndl org	20280	0.20078	<.0001
Mult mye w/o achv rmson	20300	0.41084	<.0001
Ch lym leuk wo achv rmsn	20410	0.37957	<.0001
Essntial thrombocythemia	23871	0.12789	0.0003
Low grde myelody syn les	23872	0.15381	0.0017
Myelodysplastic synd NOS	23875	0.20555	<.0001
DMII wo cmp nt st uncntr	25000	0.0721	<.0001
DMII wo cmp uncntrld	25002	-0.01161	0.0705
DMII keto nt st uncntrld	25010	0.0982	0.0001
DMII ketoacd uncontrold	25012	0.14458	<.0001
DMI ketoacd uncontrold	25013	0.28449	<.0001
DMII hprosmlr uncontrold	25022	0.04571	0.2251
DMII renl nt st uncntrld	25040	0.03375	<.0001
DMI renl nt st uncntrld	25041	0.07679	<.0001
DMII ophth nt st uncntrl	25050	0.00575	0.482
DMI ophth uncntrld	25053	0.0629	0.0443
DMII neuro nt st uncntrl	25060	-0.00885	0.2742
DMI neuro nt st uncntrld	25061	0.03226	0.0203
DMII neuro uncntrld	25062	-0.004	0.7193
DMI neuro uncntrld	25063	0.05321	0.037
DMII circ nt st uncntrld	25070	-0.01444	0.0857
DMI circ nt st uncntrld	25071	-0.02272	0.1652
DMII circ uncntrld	25072	0.00435	0.7765
DMII oth nt st uncntrld	25080	0.12132	<.0001
DMI oth nt st uncntrld	25081	0.09973	<.0001
DMII oth uncntrld	25082	0.05006	0.0001
DMI oth uncntrld	25083	0.14618	<.0001
Glucocorticoid deficient	25541	0.31984	<.0001
Amyloidosis NEC	27739	0.32816	<.0001
Metabolism disorder NEC	27789	0.13233	0.0078
Morbid obesity	27801	0.00932	0.3779
Obesity hypovent synd	27803	-0.02953	0.3107
Sickle cell disease NOS	28260	0.61472	<.0001
Antin chemo indcd pancyt	28411	0.39212	<.0001
Other pancytopenia	28419	0.17159	<.0001
Neutropenia NOS	28800	0.19529	<.0001

ICD-9 Description	ICD-9 Code	Coefficient	P-value
Drug induced neutropenia	28803	0.29116	<.0001
Prim hypercoagulable st	28981	0.15977	<.0001
Senile delusion	29020	0.1114	0.0105
Vascular dementia,uncomp	29040	0.10829	<.0001
Dementia w/o behav dist	29410	0.10461	<.0001
Dementia w behavior dist	29411	0.12167	<.0001
Demen NOS w/o behv dstrb	29420	0.15134	<.0001
Schizophrenia NOS-unspec	29590	0.16904	<.0001
Depress psychosis-unspec	29620	0.08783	<.0001
Recurr depr psychos-unsp	29630	0.04595	0.0459
Recur depr psych-severe	29633	0.04953	0.0214
Bipolar disorder NOS	29680	0.03951	0.0718
Bipolar disorder NEC	29689	0.0765	0.1406
Episodic mood disord NOS	29690	-0.0061	0.8254
Alcoh dep NEC/NOS-unspec	30390	0.02262	0.4481
Alcoh dep NEC/NOS-remiss	30393	-0.0592	0.1194
Opioid dependence-unspec	30400	0.23963	<.0001
Opioid dependence-contin	30401	0.10216	0.0083
Drug depend NOS-unspec	30490	0.09283	0.0412
Psymotr epil w/o int epi	34540	-0.05696	0.1739
Epilep NOS w/o intr epil	34590	0.10419	<.0001
Critical illness myopthy	35981	-0.10948	0.0009
Prolif diab retinopathy	36202	-0.056	<.0001
Mod nonprolf db retinoph	36205	-0.10539	0.0017
Diabetic macular edema	36207	-0.16216	<.0001
Hyp ht dis NOS w ht fail	40291	-0.01224	0.5579
Subendo infarct, initial	41071	0.28073	<.0001
AMI NEC, unspecified	41080	-0.00835	0.8738
AMI NOS, unspecified	41090	0.04091	0.0037
Ac ischemic hrt dis NEC	41189	0.07088	0.0013
Pulm embol/infarct NEC	41519	0.02084	0.2221
Atrial fibrillation	42731	0.24876	<.0001
Atrial flutter	42732	0.06245	<.0001
Sinoatrial node dysfunct	42781	-0.04157	<.0001
Crbl emblsm w infrct	43411	0.18777	<.0001
Crbl art ocl NOS w infrc	43491	0.12749	<.0001
Athscl extrm ntv art NOS	44020	0.02718	0.0013
Ath ext ntv at w claudct	44021	0.02956	0.0173
Ath ext ntv at w rst pn	44022	0.0837	<.0001
Ath ext ntv art ulcrtion	44023	0.05416	<.0001

ICD-9 Description	ICD-9 Code	Coefficient	P-value
Dsct of thoracic aorta	44101	0.11966	0.0452
Periph vascular dis NEC	44389	0.02878	0.0596
Deep phlebitis-leg NEC	45119	-0.04641	0.1151
Ac DVT/emb prox low ext	45341	0.08701	<.0001
Ch DVT/embl low ext NOS	45350	0.05663	0.1025
Ch DVT/embl prox low ext	45351	0.03822	0.3528
Ch emblsm subclav veins	45375	0.16767	<.0001
Ac DVT/embl up ext	45382	0.07744	0.0026
Ac emblsm axillary veins	45384	0.07944	0.049
Ac embl internl jug vein	45386	0.08068	0.0006
Ac embl thorac vein NEC	45387	0.07384	0.0288
Esoph varice oth dis NOS	45621	0.18859	<.0001
Obs chr bronc w(ac) exac	49121	0.13193	<.0001
Obs chr bronc w ac bronc	49122	-0.0088	0.5824
Chronic obst asthma NOS	49320	0.01834	0.1388
Ch obst asth w (ac) exac	49322	0.01286	0.4885
Ac resp flr fol trma/srg	51851	0.02845	0.355
Ot pul insuf fol trm/srg	51852	-0.06297	0.3178
Other pulmonary insuff	51882	0.09857	<.0001
Chronic respiratory fail	51883	0.11434	<.0001
Acute & chronc resp fail	51884	0.12628	<.0001
Gastrostomy comp - mech	53642	0.15365	<.0001
Fecal impaction	56032	0.04821	0.1281
Pressure ulcer, low back	70703	0.22465	<.0001
Pressure ulcer, hip	70704	0.24053	<.0001
Pressure ulcer, buttock	70705	0.09838	<.0001
Ulcer of lower limb NOS	70710	0.09412	<.0001
Ulcer other part of foot	70715	0.08756	<.0001
Ulcer oth part low limb	70719	0.16587	<.0001
Pyogen arthritis-unspec	71100	-0.04327	0.3753
Pyogen arthritis-l/leg	71106	0.02859	0.4542
Ac osteomyelitis-unspec	73000	-0.04987	0.131
Ac osteomyelitis-ankle	73007	-0.08917	<.0001
Ac osteomyelitis NEC	73008	-0.03235	0.307
Osteomyelitis NOS-hand	73024	0.24478	<.0001
Osteomyelitis NOS-ankle	73027	-0.12149	<.0001
Path fx vertebrae	73313	0.22531	<.0001
Aseptic necrosis femur	73342	0.10754	0.0188
Asept necrosis bone NEC	73349	0.15539	0.006
Coma	78001	0.21242	<.0001

ICD-9 Description	ICD-9 Code	Coefficient	P-value
Convulsions NEC	78039	0.09323	<.0001
Fx femur intrcaps NEC-cl	82009	-0.00952	0.7647
Fx femur NOS-closed	82100	-0.02136	0.4055
React-indwell urin cath	99664	0.05432	0.0555
Compl heart transplant	99683	0.09947	0.1582
Asymp hiv infectn status	V08	0.46221	<.0001
Heart transplant status	V421	0.19932	0.0002
Liver transplant status	V427	0.03733	0.2656
Trnspl status-pancreas	V4283	0.1358	0.0026
Gastrostomy status	V441	0.02576	0.2534
Ileostomy status	V442	-0.07135	0.0349
Colostomy status	V443	0.01882	0.4186
Urinostomy status NEC	V446	0.27221	<.0001
Respirator depend status	V4611	0.08244	<.0001
Status amput othr toe(s)	V4972	-0.02421	0.1067
Status amput below knee	V4975	0.14259	<.0001
Status amput above knee	V4976	0.09281	<.0001
Atten to gastrostomy	V551	-0.05311	0.0197
Long-term use of insulin	V5867	0.0585	<.0001
BMI 40.0-44.9, adult	V8541	-0.03968	0.0375
Less than 6 months of Medicare eligible claims in the previous calendar year		0.53332	<.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 multicollinearity among covariates, likely resulting in some unexpected results in direction of 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 initial and current health condition of the patient in risk adjustment.

2019 Submission

Table 4 presents results for the selected clinical and patient risk factors for the baseline SMR model.

Table 4. Base Model Coefficients, Data Years 2015–2018.

Covariate	Coefficient	P Value^	Hazard Ratio^
Age			
Age (continuous)	-0.07	--	--

Covariate	Coefficient	P Value^	Hazard Ratio^
Age spline at 14	0.10	--	--
Age spline at 60	0.01	--	--
Race			
White	Reference		
Black	-0.30	--	--
Asian Pacific Islander	-0.37	--	--
Native American	-0.12	--	--
Other	-0.42	--	--
Interaction: Black Race and			
Age (continuous)	0.01	0.77	1.01
Age spline at 14	-0.01	0.68	0.99
Age spline at 60	0.002	0.03	1.00
Interaction: Diabetes as cause of ESRD and			
Asian	0.06	0.001	1.06
Black	-0.08	<.0001	0.92
Native American	-0.01	0.91	1.00
Other	0.14	0.08	1.15
Ethnicity			
Non-Hispanic ethnicity	Reference		
Hispanic	-0.31	--	--
Unknown ethnicity	-0.27	--	--
Interaction: Nonwhite race and:			
Hispanic	0.27	<.0001	1.31
Unknown ethnicity	-0.03	0.67	0.97
Sex: female	-0.08	--	--
Interaction: Black race x female Sex	0.04	<.0001	1.05
Cause of ESRD			
Diabetes	0.19	--	--
Missing	0.13	0.0009	1.14
BMI			
BMI < 18.5	0.31	<.0001	1.36
18.5 ⩽ BMI < 25	0.16	<.0001	1.17
25⩽ BMI < 30	0.05	<.0001	1.06
BMI ⩾30	Reference		
Calendar Year			
2015	0.06	<.0001	1.06
2016	0.02	<.0001	1.02
2017	0.004	0.39	1.00
2018	Reference		
Time on ESRD			

Covariate	Coefficient	P Value^	Hazard Ratio^
0-1 Years	-0.38	--	--
1-2 Years	-0.24	--	--
2-3 Years	-0.18	--	--
3+ Years	Reference		
Interaction: Time on ESRD: < 1 year and:			
Asian	-0.11	<.0001	0.89
Black	0.06	<.0001	1.06
Native American	-0.07	0.17	0.93
Other	-0.03	0.74	0.97
Interaction: Diabetes as cause of ESRD and:			
0-1 Years with ESRD	-0.23	<.0001	0.80
1-2 Years with ESRD	-0.10	<.0001	0.91
2-3 Years with ESRD	-0.03	0.01	0.97
Comorbidities at start of ESRD			
Atherosclerotic heart	0.06	<.0001	1.07
Other cardiac disease	0.08	<.0001	1.09
Congestive heart failure	0.13	<.0001	1.13
Inability to ambulate	0.14	<.0001	1.15
Chronic obstructive pulmonary disease	0.08	<.0001	1.08
Inability to transfer	0.07	<.0001	1.07
Malignant neoplasm, Cancer	0.10	<.0001	1.10
Diabetes	0.04	<.0001	1.04
Peripheral vascular disease	0.06	<.0001	1.06
Cerebrovascular disease, CVA, TIA	0.02	0.01	1.02
Tobacco use (current smoker)	0.15	<.0001	1.16
Alcohol dependence	0.02	0.33	1.02
Drug dependence	0.14	<.0001	1.15
At least one of the comorbidities listed	0.10	<.0001	1.11
No Medical Evidence (CMS-2728)	0.43	<.0001	1.54
Nursing home during the prior 365 days			
No nursing home care (0 days)	Reference		
Short-term nursing home care (1-89 days)	0.43	<.0001	1.54
Long-term nursing home care (>=90 days)	0.48	<.0001	1.62
Prevalent Comorbidities (condition groups)			
Candidal esophagitis	0.12	<.0001	1.13
Sarcoidosis	0.08	0.01	1.09
Cancer of Liver	0.84	<.0001	2.31
Cancer of Lung	0.69	<.0001	2.00
Cancer of Prostate	0.07	0.002	1.08
Cancer of Bladder	0.37	<.0001	1.45

Covariate	Coefficient	P Value^	Hazard Ratio^
Cancer of Kidney	0.07	0.003	1.07
Cancer of Bone	0.66	<.0001	1.93
Other Neoplasm	0.31	<.0001	1.36
Non-Hodgkins Lymphoma	0.24	<.0001	1.27
Multiple Myeloma	0.43	<.0001	1.54
Chronic lymphoid leukemia	0.28	<.0001	1.32
Myelodysplastic Syndrome	0.23	<.0001	1.26
Essential Thrombocytopenia	0.13	<.0001	1.14
Diabetes without complications	0.04	<.0001	1.04
Diabetes with complications	0.11	<.0001	1.11
Glucocorticoid deficiency	0.29	<.0001	1.34
Malnutrition / Cachexia	0.28	<.0001	1.32
Disorders of urea cycle metabolism	0.19	<.0001	1.21
Other amyloidosis	0.25	<.0001	1.28
Other specified disorders of metabolism	0.05	0.001	1.05
Morbid Obesity	-0.05	<.0001	0.95
Sickle-cell Anemia	0.45	<.0001	1.56
Pancytopenia	0.19	<.0001	1.21
Neutropenia	0.15	<.0001	1.17
Primary hypercoagulable state	0.05	0.03	1.05
Dementia	0.18	<.0001	1.20
Substance Related Disorders	0.11	0.001	1.12
Miscellaneous Mental Health	0.06	0.28	1.06
Opioid Dependance	0.17	<.0001	1.18
Schizophrenia	0.11	<.0001	1.12
Cerebral degeneration, unspecified	0.04	0.26	1.04
Peripheral autonomic neuropathy in disorders classified elsewhere	0.06	0.09	1.06
Unspecified hereditary and idiopathic peripheral neuropathy	0.03	0.02	1.03
Epilepsy	0.11	<.0001	1.12
Bipolar Disorder	0.07	<.0001	1.07
Major depressive affective disorder	0.10	<.0001	1.10
Mood Disorders	0.07	0.02	1.07
Alcohol Related Disorders	0.05	0.01	1.05
Coma	0.31	<.0001	1.36
Cerebral edema	0.25	<.0001	1.28
Critical illness myopathy	-0.16	<.0001	0.86
hypertensive heart disease with heart failure	0.01	0.74	1.01
Myocardial Infarction	0.22	<.0001	1.25
Coronary Atherosclerosis	0.08	<.0001	1. 09
Pulmonary embolism and infarction	0.13	<.0001	1.14

Covariate	Coefficient	P Value^	Hazard Ratio^
Primary pulmonary hypertension	0.11	0.02	1.12
Pulmonary Heart Disease	0.19	<.0001	1.21
Cardiomyopathy	0.19	<.0001	1.22
Atrioventricular block, complete	0.07	<.001	1.07
Paroxysmal Tachycardia	0.20	<.0001	1.22
Atrial fibrillation	0.21	<.0001	1.24
Atrial flutter	0.05	<.0001	1.05
Sinoatrial node dysfunction	-0.04	<.0001	0.96
Acute Cerebrovascular Disease	0.13	<.0001	1.14
Peripheral and Visceral Atherosclerosis	0.15	<.0001	1.16
Venous Thromboembolism	0.09	<.0001	1.09
Esophageal varices	0.22	<.0001	1.25
Chronic Obstructive Pulmonary Disease	0.13	<.0001	1.14
Asthma	0.03	0.00	1.03
Aspiration Pneumonitis	0.12	<.0001	1.13
Other Lower Respiratory Diseases	0.19	<.0001	1.21
Respiratory Failure	0.18	<.0001	1.20
Enteritis and Ulcerative Colitis	0.06	0.01	1.07
Ileus and Intestinal Obstruction	-0.01	0.36	0.99
Cirrhosis of Liver	0.37	<.0001	1.45
Other Liver Disease	0.27	<.0001	1.31
Pancreatitis	0.17	<.0001	1.18
Chronic Skin Ulcer	0.26	<.0001	1.29
Systemic lupus erythematosus and connective tissue disorders	0.23	<.0001	1.26
Infective arthritis and osteomyelitis	-0.12	<.0001	0.88
Rheumatoid Arthritis	0.08	<.0001	1.08
Pathologic Fracture	0.16	<.0001	1.18
Aseptic Necrosis	0.01	0.86	1.01
Hip and Femur Fracture	-0.02	0.36	0.98
Gangrene	0.16	<.0001	1.17
Infection due to urinary catheter	0.002	0.92	1.00
HIV	0.22	<.0001	1.24
Solid Organ Transplant	0.04	0.05	1.04
Gastrostomy status	0.09	<.0001	1.09
Ileostomy / Colostomy Status	0.01	0.41	1.01
Other artificial opening of urinary tract status	0.15	<.0001	1.16
Dependence on respirator, status	0.05	0.03	1.05
Other toe(s) amputation status	0.02	0.15	1.02
Below knee amputation status	0.11	<.0001	1.12
Above knee amputation status	0.14	<.0001	1.16

Covariate	Coefficient	P Value^	Hazard Ratio^
Long-term (current) use of insulin	0.03	<.0001	1.03
Cancer of Rectum	0.34	<.0001	1.40
Inflammatory polyarthropathy	0.12	0.14	1.13
Sacroiliitis	-0.006	0.95	1.00
Less than 6 Medicare covered months in prior calendar year	0.54	<.0001	1.71

^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 black race means that the effect of female depends on race.

4.5.6 Analyses and Interpretation in Selection of Social Risk Factors (NQF Testing Attachment 2b3.4b.)

2016 Submission

Table 4a below presents a sensitivity analysis assessing the inclusion of additional SES measures (the base model already includes race, sex, and ethnicity). It compares coefficients in the original (baseline) SMR model with and without adjustment for the SES measures.

Table 4a. Comparing coefficients between sensitivity models with and without SES adjustors, 2010-2013: Model coefficients

	Baseline SMR			SES-adjusted SMR	
Covariate	Coefficient	P-value		Coefficient	P-value
Medicare coverage*					
Medicare primary + Medicaid	NA	NA		0.01461	0.0044
Medicare primary + no Medicaid	NA	NA		Reference	-
Medicare secondary/HMO	NA	NA		0.27131	<.0001
Employment status 6 months prior to ESRD					
Unemployed	NA	NA		Reference	-
Employed	NA	NA		0.04617	<.0001
Other/Unknown	NA	NA		0.12512	<.0001
ADI element					
Home value (median)	NA	NA		0.02098	<.0001

	Baseline SMR			SES-adjusted SMR	
Covariate	**Coefficient**	**P-value**		**Coefficient**	**P-value**
Family income (median)	NA	NA		-0.01099	<.0001
Income disparity**	NA	NA		-0.00043	0.8072
Monthly mortgage (median)	NA	NA		-0.01234	0.3707
< 9 years of education (%)	NA	NA		-0.00135	0.0257
No high school diploma (%)	NA	NA		0.00346	<.0001
Home ownership rate (%)	NA	NA		0.00115	<.0001
Families below the poverty level (%)	NA	NA		0.00149	0.0093
Gross rent (median)	NA	NA		-0.03188	0.0617
Single-parent households with children <18 (%)	NA	NA		-0.00172	<.0001
Unemployment rate (%)	NA	NA		0.00194	0.1061
Comorbidities at start of ESRD					
At least one of the comorbidities listed below	0.15783	<.0001		0.15872	<.0001
Atherosclerotic heart disease	0.04559	<.0001		0.04497	<.0001
Other cardiac disease	0.06736	<.0001		0.06610	<.0001
Diabetes***	0.01596	0.0389		0.00909	0.2402
Congestive heart failure	0.12221	<.0001		0.12053	<.0001
Inability to ambulate	0.14953	<.0001		0.14973	<.0001
Chronic obstructive pulmonary disease	0.07399	<.0001		0.07118	<.0001
Inability to transfer	0.11727	<.0001		0.11738	<.0001
Malignant neoplasm, cancer	0.10791	<.0001		0.10938	<.0001
Peripheral vascular disease	0.05252	<.0001		0.05068	<.0001
Cerebrovascular disease, CVA, TIA	0.01484	0.0311		0.01500	0.0295
Tobacco use (current smoker)	0.10783	<.0001		0.10764	<.0001
Alcohol dependence	0.03135	0.0989		0.03031	0.1118
Drug dependence	0.07436	0.0008		0.07526	0.0008

	Baseline SMR			SES-adjusted SMR	
Covariate	**Coefficient**	**P-value**		**Coefficient**	**P-value**
No Medical Evidence (CMS-2728) Form	0.0115	0.7696		0.02392	0.5432
Cause of ESRD					
Diabetes	0.14834	<.0001		0.14697	<.0001
Missing	-0.02574	0.2855		-0.02566	0.2876
Sex: Female	-0.07704	<.0001		-0.07910	<.0001
Age					
Continuous (years)	-0.05786	0.0003		-0.04705	0.0049
Spline at 14 years	0.08753	<.0001		0.07640	<.0001
Spline at 60 years	0.00651	<.0001		0.00687	<.0001
Race: black X age interaction					
Continuous (years)	-0.0371	0.1983		-0.04956	0.0899
Spline at 14 years	0.03412	0.2384		0.04682	0.1104
Spline at 60 years	0.0009396	0.4437		0.00019	0.8764
In nursing home the previous year	0.31026	<.0001		0.30617	<.0001
Incident BMI					
Log BMI (continuous)	-0.48904	<.0001		-0.49342	<.0001
Log BMI (spline at 35)	0.57016	<.0001		0.57780	<.0001
BMI missing	0.14771	<.0001		0.09123	<.0001
Race					
White	Reference	-		Reference	-
Black	0.31856	0.4275		0.47373	0.2443
Asian/PI	-0.33283	<.0001		-0.32944	<.0001
Native American	-0.12939	0.0015		-0.14447	0.0004
Other/unknown	-0.25062	<.0001		-0.24259	<.0001
Time on ESRD					

	Baseline SMR			SES-adjusted SMR	
Covariate	**Coefficient**	**P-value**		**Coefficient**	**P-value**
< 1 year	-0.18009	<.0001		-0.15762	<.0001
1 to 2 years	-0.21764	<.0001		-0.22296	<.0001
2 to 3 years	-0.17079	<.0001		-0.17220	<.0001
3+ years	Reference	-		Reference	-
Calendar year					
2010	0.1289	<.0001		0.12868	<.0001
2011	0.10334	<.0001		0.10466	<.0001
2012	0.00509	0.3735		0.00637	0.2659
2013	Reference	-		Reference	-
Ethnicity					
Hispanic	-0.31125	<.0001		-0.31963	<.0001
Non-Hispanic ethnicity	Reference	-		Reference	-
Unknown ethnicity	0.09259	0.0082		0.04305	0.2247
Ethnicity X race: nonwhite interaction				0.04305	0.2247
Hispanic ethnicity	0.30208	<.0001		0.29982	<.0001
Unknown ethnicity	0.12773	0.0004		0.13890	0.0001
Race X diabetes as cause of ESRD interaction					
Asian/PI	0.04491	0.0405		0.04655	0.0342
Black	-0.08505	<.0001		-0.08224	<.0001
Native American	-0.00639	0.8865		-0.00422	0.9251
Other	0.10269	0.0266		0.09440	0.0422
Time with ESRD X diabetes as cause of ESRD interaction					
< 1 year	-0.20115	<.0001		-0.20451	<.0001
1 to 2 years	-0.11321	<.0001		-0.11674	<.0001
2 to 3 years	-0.04516	0.0004		-0.04722	0.0002

Covariate	Baseline SMR			SES-adjusted SMR	
	Coefficient	P-value		Coefficient	P-value
3+ years	Reference	-		Reference	-
Time on ESRD: < 1 year X race interaction					
Asian/PI	-0.13672	<.0001		-0.12823	<.0001
Black	0.03974	0.0003		0.03854	0.0005
Native American	-0.10883	0.0344		-0.08779	0.0889
Other	0.26902	<.0001		0.28112	<.0001
Time on ESRD: < 1 year X sex: female interaction	0.00915	0.3193		0.01012	0.2716
Sex: female X cause of ESRD: diabetes interaction	-0.00839	0.3009		-0.00766	0.3454
Race: black X sex: female interaction	0.06686	<.0001		0.06466	<.0001

*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 4b presents a sensitivity analysis of inclusion of additional SES measures. It compares coefficients for the prevalent comorbidities that were added into the baseline SMR model to the model with adjustment for additional SES measures.

Table 4b. Comparing coefficients between sensitivity models with and without SDS/SES adjustors, 2010-2013: Prevalent comorbidity coefficients

ICD-9 Description	ICD-9 Code	Baseline SMR		SES-adjusted SMR	
		Coefficient	P-value	Coefficient	P-value
Protein-cal malnutr NOS	2639	0.19068	<.0001	0.18507	<.0001
Aut neuropthy in oth dis	3371	0.02175	0.1983	0.01961	0.2463
Epilep NOS w/o intr epil	34590	0.10419	<.0001	0.09632	<.0001
Cerebral edema	3485	0.21974	<.0001	0.21941	<.0001

ICD-9 Description	ICD-9 Code	Baseline SMR		SES-adjusted SMR	
		Coefficient	P-value	Coefficient	P-value
Subendo infarct, initial	41071	0.28073	<.0001	0.26653	<.0001
AMI NEC, unspecified	41080	-0.00835	0.8738	-0.00041	0.9938
AMI NOS, unspecified	41090	0.04091	0.0037	0.05808	<.0001
Intermed coronary synd	4111	0.05768	<.0001	0.05824	<.0001
Ac ischemic hrt dis NEC	41189	0.07088	0.0013	0.07115	0.0013
Angina pectoris NEC/NOS	4139	0.00621	0.5314	0.01037	0.2964
Cardiomyopath in oth dis	4258	0.04292	0.0329	0.04335	0.0312
Atriovent block complete	4260	0.15129	<.0001	0.15412	<.0001
Parox ventric tachycard	4271	0.18283	<.0001	0.18208	<.0001
Parox tachycardia NOS	4272	0.07202	0.0747	0.07677	0.0578
Atrial fibrillation	42731	0.24876	<.0001	0.24872	<.0001
Atrial flutter	42732	0.06245	<.0001	0.05850	<.0001
Sinoatrial node dysfunct	42781	-0.04157	<.0001	-0.03410	0.0007
Subdural hemorrhage	4321	0.13039	<.0001	0.13410	<.0001
Stricture of artery	4471	-0.02833	0.0635	-0.02009	0.1885
Paralytic ileus	5601	-0.01047	0.5007	-0.01566	0.3137
Convulsions NEC	78039	0.09323	<.0001	0.09773	<.0001
Gangrene	7854	0.17237	<.0001	0.16491	<.0001
Cachexia	7994	0.33328	<.0001	0.32915	<.0001
Candidal esophagitis	11284	0.21728	<.0001	0.21573	<.0001
Sarcoidosis	135	0.0498	0.1881	0.05122	0.1762
Malignant neopl rectum	1541	0.30273	<.0001	0.30444	<.0001
Mal neo liver, primary	1550	0.36764	<.0001	0.36945	<.0001
Mal neo upper lobe lung	1623	0.27901	<.0001	0.27482	<.0001
Mal neo bronch/lung NOS	1629	0.41213	<.0001	0.41821	<.0001

ICD-9 Description	ICD-9 Code	Baseline SMR		SES-adjusted SMR	
		Coefficient	P-value	Coefficient	P-value
Malign neopl prostate	185	-0.06496	<.0001	-0.05553	0.0002
Malig neo bladder NOS	1889	0.19631	<.0001	0.20432	<.0001
Malig neopl kidney	1890	-0.04592	0.0198	-0.04201	0.0332
Malign neopl thyroid	193	-0.24613	<.0001	-0.24139	<.0001
Secondary malig neo lung	1970	0.5234	<.0001	0.51907	<.0001
Second malig neo liver	1977	0.90921	<.0001	0.89766	<.0001
Secondary malig neo bone	1985	0.71735	<.0001	0.72095	<.0001
Malignant neoplasm NOS	1991	0.35314	<.0001	0.35642	<.0001
Oth lymp unsp xtrndl org	20280	0.20078	<.0001	0.19980	<.0001
Mult mye w/o achv rmson	20300	0.41084	<.0001	0.41119	<.0001
Ch lym leuk wo achv rmsn	20410	0.37957	<.0001	0.37275	<.0001
Essntial thrombocythemia	23871	0.12789	0.0003	0.12778	0.0003
Low grde myelody syn les	23872	0.15381	0.0017	0.15872	0.0012
Myelodysplastic synd NOS	23875	0.20555	<.0001	0.20504	<.0001
DMII wo cmp nt st uncntr	25000	0.0721	<.0001	0.08063	<.0001
DMII wo cmp uncntrld	25002	-0.01161	0.0705	-0.00322	0.616
DMII keto nt st uncntrld	25010	0.0982	0.0001	0.10744	<.0001
DMII ketoacd uncontrold	25012	0.14458	<.0001	0.13872	<.0001
DMI ketoacd uncontrold	25013	0.28449	<.0001	0.27018	<.0001
DMII hprosmlr uncontrold	25022	0.04571	0.2251	0.03856	0.3067
DMII renl nt st uncntrld	25040	0.03375	<.0001	0.03346	<.0001
DMI renl nt st uncntrld	25041	0.07679	<.0001	0.08050	<.0001
DMII ophth nt st uncntrl	25050	0.00575	0.482	0.00487	0.5519
DMI ophth uncntrld	25053	0.0629	0.0443	0.05910	0.0592
DMII neuro nt st uncntrl	25060	-0.00885	0.2742	-0.00427	0.5978

ICD-9 Description	ICD-9 Code	Baseline SMR		SES-adjusted SMR	
		Coefficient	P-value	Coefficient	P-value
DMI neuro nt st uncntrld	25061	0.03226	0.0203	0.03699	0.0078
DMII neuro uncntrld	25062	-0.004	0.7193	-0.00338	0.7615
DMI neuro uncntrld	25063	0.05321	0.037	0.05173	0.0429
DMII circ nt st uncntrld	25070	-0.01444	0.0857	-0.00987	0.2409
DMI circ nt st uncntrld	25071	-0.02272	0.1652	-0.01331	0.4165
DMII circ uncntrld	25072	0.00435	0.7765	0.00623	0.6842
DMII oth nt st uncntrld	25080	0.12132	<.0001	0.11796	<.0001
DMI oth nt st uncntrld	25081	0.09973	<.0001	0.09945	<.0001
DMII oth uncntrld	25082	0.05006	0.0001	0.04745	0.0003
DMI oth uncntrld	25083	0.14618	<.0001	0.14627	<.0001
Glucocorticoid deficient	25541	0.31984	<.0001	0.31685	<.0001
Oth severe malnutrition	262	0.17484	<.0001	0.16782	<.0001
Dis urea cycle metabol	2706	-0.01549	0.7273	-0.01721	0.6988
Amyloidosis NEC	27739	0.32816	<.0001	0.32030	<.0001
Metabolism disorder NEC	27789	0.13233	0.0078	0.13012	0.0089
Morbid obesity	27801	0.00932	0.3779	0.00456	0.6664
Obesity hypovent synd	27803	-0.02953	0.3107	-0.03330	0.253
Sickle cell disease NOS	28260	0.61472	<.0001	0.60712	<.0001
Antin chemo indcd pancyt	28411	0.39212	<.0001	0.36961	<.0001
Other pancytopenia	28419	0.17159	<.0001	0.16941	<.0001
Neutropenia NOS	28800	0.19529	<.0001	0.19467	<.0001
Drug induced neutropenia	28803	0.29116	<.0001	0.29394	<.0001
Prim hypercoagulable st	28981	0.15977	<.0001	0.15749	<.0001
Senile dementia uncomp	2900	0.07334	<.0001	0.08098	<.0001
Senile delusion	29020	0.1114	0.0105	0.11073	0.011

ICD-9 Description	ICD-9 Code	Baseline SMR		SES-adjusted SMR	
		Coefficient	P-value	Coefficient	P-value
Vascular dementia,uncomp	29040	0.10829	<.0001	0.11062	<.0001
Drug withdrawal	2920	0.13901	0.0014	0.13186	0.0024
Dementia w/o behav dist	29410	0.10461	<.0001	0.10741	<.0001
Dementia w behavior dist	29411	0.12167	<.0001	0.13003	<.0001
Demen NOS w/o behv dstrb	29420	0.15134	<.0001	0.15265	<.0001
Mental disor NEC oth dis	2948	0.16473	<.0001	0.16480	<.0001
Schizophrenia NOS-unspec	29590	0.16904	<.0001	0.16688	<.0001
Depress psychosis-unspec	29620	0.08783	<.0001	0.08581	<.0001
Recurr depr psychos-unsp	29630	0.04595	0.0459	0.04318	0.0608
Recur depr psych-severe	29633	0.04953	0.0214	0.05826	0.0068
Bipolar disorder NOS	29680	0.03951	0.0718	0.03852	0.0792
Bipolar disorder NEC	29689	0.0765	0.1406	0.07663	0.14
Episodic mood disord NOS	29690	-0.0061	0.8254	-0.00805	0.7711
Alcoh dep NEC/NOS-unspec	30390	0.02262	0.4481	0.01772	0.5525
Alcoh dep NEC/NOS-remiss	30393	-0.0592	0.1194	-0.06103	0.1081
Opioid dependence-unspec	30400	0.23963	<.0001	0.23251	<.0001
Opioid dependence-contin	30401	0.10216	0.0083	0.09609	0.0131
Drug depend NOS-unspec	30490	0.09283	0.0412	0.09262	0.0415
Cereb degeneration NOS	3319	0.10725	<.0001	0.11542	<.0001
Grand mal status	3453	-0.00454	0.8984	-0.00611	0.8635
Psymotr epil w/o int epi	34540	-0.05696	0.1739	-0.05466	0.1919
Anoxic brain damage	3481	0.2873	<.0001	0.28681	<.0001
Idio periph neurpthy NOS	3569	0.03128	0.0003	0.03480	<.0001
Neuropathy in diabetes	3572	0.0258	0.0042	0.01952	0.0303
Critical illness myopthy	35981	-0.10948	0.0009	-0.10703	0.0011

ICD-9 Description	ICD-9 Code	Baseline SMR		SES-adjusted SMR	
		Coefficient	P-value	Coefficient	P-value
Prolif diab retinopathy	36202	-0.056	<.0001	-0.04794	<.0001
Mod nonprolf db retinoph	36205	-0.10539	0.0017	-0.09839	0.0034
Diabetic macular edema	36207	-0.16216	<.0001	-0.15551	<.0001
Hyp ht dis NOS w ht fail	40291	-0.01224	0.5579	-0.00822	0.6944
Pulm embol/infarct NEC	41519	0.02084	0.2221	0.02418	0.1565
Prim pulm hypertension	4160	0.05884	0.0002	0.07312	<.0001
Chr pulmon heart dis NEC	4168	0.1898	<.0001	0.18235	<.0001
Prim cardiomyopathy NEC	4254	0.23084	<.0001	0.22949	<.0001
Crbl emblsm w infrct	43411	0.18777	<.0001	0.18506	<.0001
Crbl art ocl NOS w infrc	43491	0.12749	<.0001	0.13064	<.0001
Aortic atherosclerosis	4400	0.03595	0.0233	0.03158	0.0465
Athscl extrm ntv art NOS	44020	0.02718	0.0013	0.03302	<.0001
Ath ext ntv at w claudct	44021	0.02956	0.0173	0.03543	0.0044
Ath ext ntv at w rst pn	44022	0.0837	<.0001	0.08269	<.0001
Ath ext ntv art ulcrtion	44023	0.05416	<.0001	0.05839	<.0001
Dsct of thoracic aorta	44101	0.11966	0.0452	0.11933	0.0462
Lower extremity aneurysm	4423	0.02375	0.4642	0.02257	0.487
Periph vascular dis NEC	44389	0.02878	0.0596	0.03332	0.0294
Periph vascular dis NOS	4439	0.16444	<.0001	0.16631	<.0001
Deep phlebitis-leg NEC	45119	-0.04641	0.1151	-0.03405	0.2481
Oth inf vena cava thromb	4532	0.30687	<.0001	0.29469	<.0001
Ac DVT/emb prox low ext	45341	0.08701	<.0001	0.07657	0.0001
Ch DVT/embl low ext NOS	45350	0.05663	0.1025	0.05742	0.0979
Ch DVT/embl prox low ext	45351	0.03822	0.3528	0.03670	0.3723
Ch emblsm subclav veins	45375	0.16767	<.0001	0.16457	0.0001

ICD-9 Description	ICD-9 Code	Baseline SMR		SES-adjusted SMR	
		Coefficient	P-value	Coefficient	P-value
Ac DVT/embl up ext	45382	0.07744	0.0026	0.07820	0.0023
Ac emblsm axillary veins	45384	0.07944	0.049	0.07311	0.0702
Ac embl internl jug vein	45386	0.08068	0.0006	0.07453	0.0016
Ac embl thorac vein NEC	45387	0.07384	0.0288	0.07472	0.0269
Esoph varice oth dis NOS	45621	0.18859	<.0001	0.18789	<.0001
Obs chr bronc w(ac) exac	49121	0.13193	<.0001	0.12911	<.0001
Obs chr bronc w ac bronc	49122	-0.0088	0.5824	-0.00995	0.5339
Emphysema NEC	4928	0.07809	<.0001	0.08582	<.0001
Chronic obst asthma NOS	49320	0.01834	0.1388	0.01747	0.1583
Ch obst asth w (ac) exac	49322	0.01286	0.4885	0.01140	0.5388
Bronchiectas w/o ac exac	4940	0.03515	0.3221	0.04016	0.2583
Chr airway obstruct NEC	496	0.16266	<.0001	0.16095	<.0001
Food/vomit pneumonitis	5070	0.1607	<.0001	0.15828	<.0001
Postinflam pulm fibrosis	515	0.15118	<.0001	0.15382	<.0001
Lung involv in oth dis	5178	0.15956	0.0088	0.15551	0.0108
Ac resp flr fol trma/srg	51851	0.02845	0.355	0.02576	0.4026
Ot pul insuf fol trm/srg	51852	-0.06297	0.3178	-0.05118	0.4168
Other pulmonary insuff	51882	0.09857	<.0001	0.10648	<.0001
Chronic respiratory fail	51883	0.11434	<.0001	0.11153	<.0001
Acute & chronc resp fail	51884	0.12628	<.0001	0.11971	<.0001
Gastrostomy comp - mech	53642	0.15365	<.0001	0.15654	<.0001
Regional enteritis NOS	5559	0.12126	0.0002	0.11992	0.0002
Ulceratve colitis unspcf	5569	0.02044	0.5561	0.02618	0.4509
Chr vasc insuff intest	5571	0.13302	<.0001	0.12928	<.0001
Fecal impaction	56032	0.04821	0.1281	0.04974	0.1165

ICD-9 Description	ICD-9 Code	Baseline SMR		SES-adjusted SMR	
		Coefficient	P-value	Coefficient	P-value
Intestinal obstruct NOS	5609	0.08494	<.0001	0.08695	<.0001
Alcohol cirrhosis liver	5712	0.15572	<.0001	0.15281	<.0001
Cirrhosis of liver NOS	5715	0.41697	<.0001	0.41478	<.0001
Hepatic encephalopathy	5722	0.31225	<.0001	0.30759	<.0001
Portal hypertension	5723	0.22903	<.0001	0.22448	<.0001
Oth sequela, chr liv dis	5728	0.2376	<.0001	0.23753	<.0001
Chronic pancreatitis	5771	0.17966	<.0001	0.17399	<.0001
Pressure ulcer, low back	70703	0.22465	<.0001	0.22107	<.0001
Pressure ulcer, hip	70704	0.24053	<.0001	0.24067	<.0001
Pressure ulcer, buttock	70705	0.09838	<.0001	0.10478	<.0001
Ulcer of lower limb NOS	70710	0.09412	<.0001	0.09780	<.0001
Ulcer other part of foot	70715	0.08756	<.0001	0.08939	<.0001
Ulcer oth part low limb	70719	0.16587	<.0001	0.16417	<.0001
Chronic skin ulcer NEC	7078	0.14188	<.0001	0.14378	<.0001
Syst lupus erythematosus	7100	0.19554	<.0001	0.19217	<.0001
Systemic sclerosis	7101	0.39484	<.0001	0.39577	<.0001
Pyogen arthritis-unspec	71100	-0.04327	0.3753	-0.03074	0.5285
Pyogen arthritis-l/leg	71106	0.02859	0.4542	0.02339	0.5399
Rheumatoid arthritis	7140	0.0896	<.0001	0.08839	<.0001
Inflamm polyarthrop NOS	7149	-0.02268	0.6699	-0.01212	0.8198
Sacroiliitis NEC	7202	0.04558	0.2878	0.05254	0.221
Ac osteomyelitis-unspec	73000	-0.04987	0.131	-0.04126	0.2117
Ac osteomyelitis-ankle	73007	-0.08917	<.0001	-0.08530	<.0001
Ac osteomyelitis NEC	73008	-0.03235	0.307	-0.02967	0.3489
Osteomyelitis NOS-hand	73024	0.24478	<.0001	0.25059	<.0001

ICD-9 Description	ICD-9 Code	Baseline SMR		SES-adjusted SMR	
		Coefficient	P-value	Coefficient	P-value
Osteomyelitis NOS-ankle	73027	-0.12149	<.0001	-0.12727	<.0001
Path fx vertebrae	73313	0.22531	<.0001	0.22783	<.0001
Aseptic necrosis femur	73342	0.10754	0.0188	0.10703	0.0194
Asept necrosis bone NEC	73349	0.15539	0.006	0.15596	0.0058
Coma	78001	0.21242	<.0001	0.21663	<.0001
Fracture of pubis-closed	8082	0.11422	0.0001	0.11024	0.0002
Pelvic fracture NOS-clos	8088	0.05103	0.1367	0.06459	0.0593
Fx femur intrcaps NEC-cl	82009	-0.00952	0.7647	-0.01431	0.6523
Fx neck of femur NOS-cl	8208	0.04397	0.0051	0.05341	0.0007
Fx femur NOS-closed	82100	-0.02136	0.4055	-0.01357	0.5972
Amput below knee, unilat	8970	-0.09002	<.0001	-0.08001	<.0001
Amputat bk, unilat-compl	8971	-0.01234	0.7926	-0.00414	0.9299
Amput above knee, unilat	8972	-0.11732	<.0001	-0.11178	<.0001
Amputat leg, unilat NOS	8974	-0.08497	0.064	-0.07749	0.0912
React-indwell urin cath	99664	0.05432	0.0555	0.05003	0.0778
Compl heart transplant	99683	0.09947	0.1582	0.10317	0.1429
Asymp hiv infectn status	V08	0.46221	<.0001	0.45689	<.0001
Heart transplant status	V421	0.19932	0.0002	0.19111	0.0003
Liver transplant status	V427	0.03733	0.2656	0.03314	0.3237
Trnspl status-pancreas	V4283	0.1358	0.0026	0.12049	0.0076
Gastrostomy status	V441	0.02576	0.2534	0.02395	0.288
Ileostomy status	V442	-0.07135	0.0349	-0.07559	0.0254
Colostomy status	V443	0.01882	0.4186	0.01801	0.4392
Urinostomy status NEC	V446	0.27221	<.0001	0.26452	<.0001
Respirator depend status	V4611	0.08244	<.0001	0.08209	<.0001

ICD-9 Description	ICD-9 Code	Baseline SMR		SES-adjusted SMR	
		Coefficient	P-value	Coefficient	P-value
Status amput othr toe(s)	V4972	-0.02421	0.1067	-0.02797	0.0622
Status amput below knee	V4975	0.14259	<.0001	0.13869	<.0001
Status amput above knee	V4976	0.09281	<.0001	0.09153	<.0001
Atten to gastrostomy	V551	-0.05311	0.0197	-0.04863	0.0326
Long-term use of insulin	V5867	0.0585	<.0001	0.05185	<.0001
BMI 40.0-44.9, adult	V8541	-0.03968	0.0375	-0.04271	0.0252
Less than 6 months of Medicare eligible claims in the previous calendar year	—	0.53332	<.0001	0.44731	<.0001

Patient-level SDS: Compared with men, women were less likely to die (OR=0.92; p<0.01). Patients of Asian/PI, Native American and Other/unknown race, respectively, all had lower odds of mortality compared to the reference group of white patients (OR=0.72, p<0.01; OR= 0.87, p<0.01; OR=0.78, p<0.01). Mortality in Black patients was not significantly different from the reference group. We did find that Hispanic patients had lower odds of mortality (OR=0.73, p<0.01), consistent with observations in previous studies

Patient-level SES: Patients employed prior to ESRD incidence, and patients with unknown employment status (OR=1.13, p<0.01) had higher odds of mortality (OR=1.05; p<0.01) compared to unemployed patients. Note that for employment categories, the "Other/Unknown" category represents a diverse patient group with regard to SES, such as students, homemakers and those who are retired. Compared with Medicare-only patients, patients with both Medicare and Medicaid (OR=1.01; p=.004) and patients with Medicare as secondary/Medicare HMO (OR=1.31; p<0.01) had higher odds of mortality. The result for dually eligible patients having higher mortality is consistent with the hypothesis that this insurance category, on average, represents an at-risk group, but further examination is needed for the higher odds of mortality for patients with Medicare as secondary payer or HMO. It is possible that these patients represent a larger portion of incident ESRD patients, which has a known higher mortality in the first year of ESRD.

Area-level SES: Areas with high measures of deprivation are likely to have higher mortality as demonstrated in the literature for the general population as well as for the ESRD population. In general, we observed small effects on odds of mortality, in the expected direction, for most of the individual indicators of area deprivation, with several achieving statistical significance. This included a low percentage of the population with a high school diploma. The percentage of single parent households

with children <18 years however had a slightly negative impact on odds of mortality. But this could be attributed to being a generally a younger population that qualifies for social assistance and Medicaid. Overall the results provide nominal support for the postulated relationships between indicators of area-level deprivation and mortality. Further analysis would need to be conducted to determine any differences in impact when combining these factors into a composite measure of area-level deprivation. But this will be subject to data availability.

The figure below shows the correlation between facility SMRs with and without adjustment for patient and area-level SES.

Figure 1. Correlation between SMR with and without SES adjustment, 2010-2013

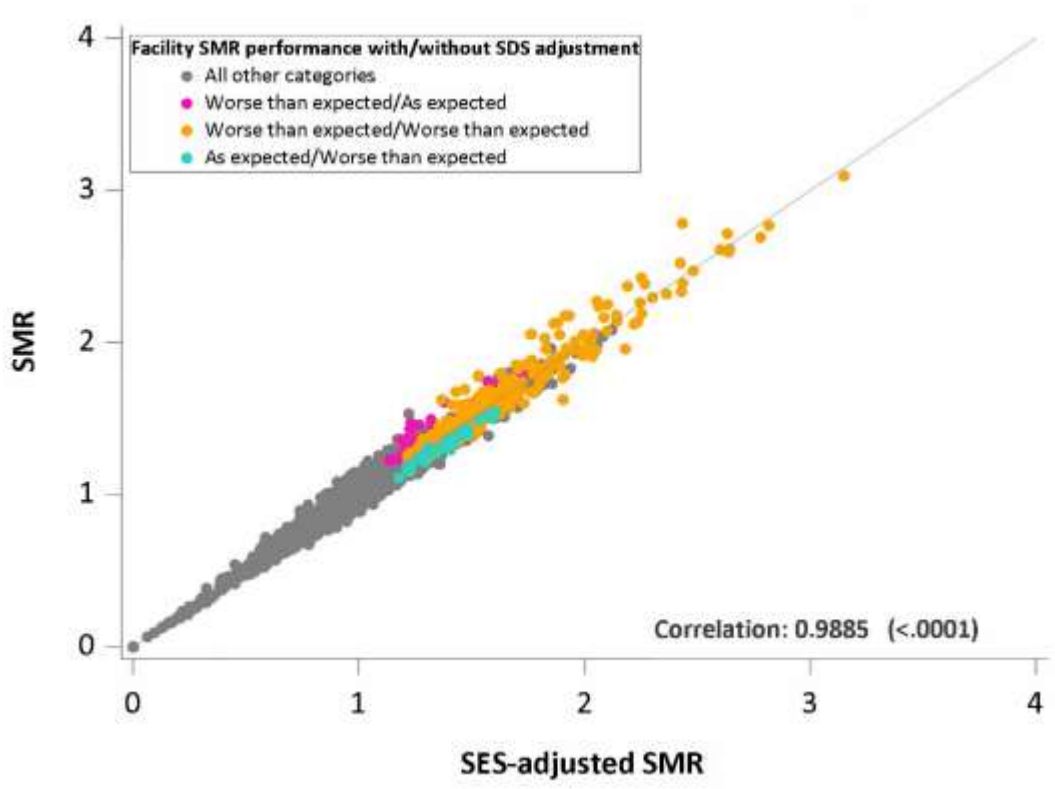

Table 5. Flagging rates, by model with and without all SES adjustors: 2010-2013

		With SES		
Without SDS *(current model)*	Better than Expected	As Expected	Worse than Expected	**Total**
Better than Expected	400	57	0	**457 (7.7%)**
As Expected	52	4938	33	**5023 (84.7%)**
Worse than Expected	0	57	393	**450 (7.6%)**
Total	**452 (7.6%)**	**5052 (85.2%)**	**426 (7.2%)**	—

After adjustment for patient and area-level SES, 199 facilities (3.4%) changed performance categories. Ninety (1.5%) facilities were down-graded, and 109 (1.8%) were upgraded.

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Table 3 below presents a sensitivity analysis assessing the inclusion of additional measure of SES/SDS (the base model already includes race, sex, and ethnicity). It compares coefficients in the original (baseline) SMR model to a model with adjustment for a set of SES measures.

Table 5. Comparing coefficients between sensitivity models with and without SES adjustors, 2015-2018: Model coefficients

	Baseline SMR			SDS/SES Adjusted SMR		
Covariate	**Coefficient**	**P Value**	**Hazard Ratio**	**Coefficient**	**P Value^**	**Hazard Ratio^**
Employment status						
Employed	--	--	--	Reference		
Unemployed	--	--	--	0.12	<.0001	1.13
Other	--	--	--	0.11	<.0001	1.11
Dual Eligible: Eligible for both Medicare and Medicaid	--	--	--	-0.01	0.01	0.99
ADI: ADI score	--	--	--	0.0002	0.22	1.00
Age						
Age (continuous)	-0.07	--	--	-0.07	--	--
Age spline at 14	0.10	--	--	0.09	--	--
Age spline at 60	0.01	--	--	0.01	--	--
Race						
White	Reference			Reference		
Black	-0.30	--	--	-0.29	--	--
Asian Pacific Islander	-0.37	--	--	-0.36	--	--
Native American	-0.12	--	--	-0.12	--	--
Other	-0.42	--	--	-0.42	--	--

	Baseline SMR			SDS/SES Adjusted SMR		
Covariate	**Coefficient**	**P Value**	**Hazard Ratio**	**Coefficient**	**P Value^**	**Hazard Ratio^**
Interaction: Black race and						
Age (continuous)	0.01	0.77	1.01	0.01	0.80	1.01
Age spline at 14	-0.01	0.68	0.99	-0.01	0.71	0.99
Age spline at 60	0.002	0.03	1.00	0.002	0.05	1.00
Interaction: Diabetes as cause of ESRD and						
Asian	0.06	0.001	1.06	0.06	0.001	1.06
Black	-0.08	<.0001	0.92	-0.08	<.0001	0.92
Native American	-0.01	0.91	1.00	-0.005	0.91	0.995
Other	0.14	0.08	1.15	0.15	0.07	1.16
Ethnicity						
Non-Hispanic ethnicity	Reference			Reference		
Hispanic	-0.31	--	--	-0.31	--	--
Unknown ethnicity	-0.27	--	--	-0.27	--	--
Interaction: Nonwhite race and						
Hispanic	0.27	<.0001	1.31	0.27	<.0001	1.31
Unknown ethnicity	-0.03	0.67	0.97	-0.03	0.65	0.97
Sex: female	-0.08	--	--	-0.08	--	--
Interaction: Black race and female sex	0.04	<.0001	1.05	0.05	<.0001	1.05
Cause of ESRD						
Diabetes	0.19	--	--	0.19	--	--
Missing	0.13	<.001	1.14	0.14	0.00	1.15
BMI						

	Baseline SMR			SDS/SES Adjusted SMR		
Covariate	**Coefficient**	**P Value**	**Hazard Ratio**	**Coefficient**	**P Value^**	**Hazard Ratio^**
BMI < 18.5	0.31	<.0001	1.36	0.31	<.0001	1.36
18.5 ⩽ BMI < 25	0.16	<.0001	1.17	0.16	<.0001	1.17
25⩽ BMI < 30	0.05	<.0001	1.06	0.05	<.0001	1.06
BMI ⩾30	Reference			Reference		
Calendar Year						
2015	0.06	<.0001	1.06	0.06	<.0001	1.06
2016	0.02	<.0001	1.02	0.02	<.0001	1.02
2017	0.004	0.39	1.00	0.00	0.44	1.00
2018	Reference			Reference		
Time on ESRD						
0-1 Years	-0.38	--	--	-0.39	--	--
1-2 Years	-0.24	<.0001	0.79	-0.25	<.0001	0.78
2-3 Years	-0.18	<.0001	0.83	-0.19	<.0001	0.83
3+ Years	Reference			Reference		
Interaction: < 1 year Time on ESRD and						
Asian	-0.11	<.0001	0.89	-0.11	<.0001	0.89
Black	0.06	<.0001	1.06	0.06	<.0001	1.06
Native American	-0.07	0.17	0.93	-0.07	0.16	0.93
Other	-0.03	0.74	0.97	-0.03	0.75	0.97
Interaction: Diabetes as cause of ESRD and						
0-1 Years with ESRD	-0.23	<.0001	0.80	-0.23	<.0001	0.80
1-2 Years with ESRD	-0.10	<.0001	0.91	-0.10	<.0001	0.91

	Baseline SMR			SDS/SES Adjusted SMR		
Covariate	**Coefficient**	**P Value**	**Hazard Ratio**	**Coefficient**	**P Value^**	**Hazard Ratio^**
2-3 Years with ESRD	-0.03	0.01	0.97	-0.03	0.01	0.97
Comorbidities at start of ESRD						
Atherosclerotic heart	0.06	<.0001	1.07	0.06	<.0001	1.07
Other cardiac disease	0.08	<.0001	1.09	0.08	<.0001	1.09
Congestive heart failure	0.13	<.0001	1.13	0.12	<.0001	1.13
Inability to ambulate	0.14	<.0001	1.15	0.14	<.0001	1.15
Chronic obstructive pulmonary disease	0.08	<.0001	1.08	0.08	<.0001	1.08
Inability to transfer	0.07	<.0001	1.07	0.07	<.0001	1.07
Malignant neoplasm, Cancer	0.10	<.0001	1.10	0.10	<.0001	1.10
Diabetes	0.04	<.0001	1.04	0.04	<.0001	1.04
Peripheral vascular disease	0.06	<.0001	1.06	0.06	<.0001	1.06
Cerebrovascular disease, CVA, TIA	0.02	0.01	1.02	0.01	0.06	1.01
Tobacco use (current smoker)	0.15	<.0001	1.16	0.15	<.0001	1.16
Alcohol dependence	0.02	0.33	1.02	0.01	0.42	1.02
Drug dependence	0.14	<.0001	1.15	0.13	<.0001	1.13
At least one of the comorbidities listed	0.10	<.0001	1.11	0.10	<.0001	1.10
No Medical Evidence (CMS-2728)	0.43	<.0001	1.54	0.40	<.0001	1.50
Nursing home during the prior 365 days						
No nursing home care (0 days)	Reference			Reference		
Short-term nursing home care (1-89 days)	0.43	<.0001	1.54	0.43	<.0001	1.53
Long-term nursing home care (>=90 days)	0.48	<.0001	1.62	0.48	<.0001	1.62

	Baseline SMR			SDS/SES Adjusted SMR		
Covariate	**Coefficient**	**P Value**	**Hazard Ratio**	**Coefficient**	**P Value^**	**Hazard Ratio^**
Prevalent Comorbidities (condition groups)						
Candidal esophagitis	0.12	<.0001	1.13	0.12	<.0001	1.13
Sarcoidosis	0.08	0.01	1.09	0.08	0.01	1.08
Cancer of Liver	0.84	<.0001	2.31	0.84	<.0001	2.31
Cancer of Lung	0.69	<.0001	2.00	0.69	<.0001	2.00
Cancer of Prostate	0.07	0.002	1.08	0.07	0.001	1.08
Cancer of Bladder	0.37	<.0001	1.45	0.37	<.0001	1.45
Cancer of Kidney	0.07	0.003	1.07	0.07	0.003	1.08
Cancer of Bone	0.66	<.0001	1.93	0.66	<.0001	1.93
Other Neoplasm	0.31	<.0001	1.36	0.31	<.0001	1.36
Non-Hodgkins Lymphoma	0.24	<.0001	1.27	0.24	<.0001	1.27
Multiple Myeloma	0.43	<.0001	1.54	0.43	<.0001	1.55
Chronic lymphoid leukemia	0.28	<.0001	1.32	0.28	<.0001	1.32
Myelodysplastic Syndrome	0.23	<.0001	1.26	0.24	<.0001	1.27
Essential Thrombocytopenia	0.13	<.0001	1.14	0.13	<.0001	1.14
Diabetes without complications	0.04	<.0001	1.04	0.05	<.0001	1.05
Diabetes with complications	0.11	<.0001	1.11	0.11	<.0001	1.11
Glucocorticoid deficiency	0.29	<.0001	1.34	0.29	<.0001	1.34
Malnutrition / Cachexia	0.28	<.0001	1.32	0.28	<.0001	1.32
Disorders of urea cycle metabolism	0.19	<.0001	1.21	0.19	<.0001	1.21
Other amyloidosis	0.25	<.0001	1.28	0.25	<.0001	1.29
Other specified disorders of metabolism	0.05	0.001	1.05	0.04	0.0009	1.05

	Baseline SMR			SDS/SES Adjusted SMR		
Covariate	**Coefficient**	**P Value**	**Hazard Ratio**	**Coefficient**	**P Value^**	**Hazard Ratio^**
Morbid Obesity	-0.05	<.0001	0.95	-0.05	<.0001	0.95
Sickle-cell Anemia	0.45	<.0001	1.56	0.44	<.0001	1.56
Pancytopenia	0.19	<.0001	1.21	0.19	<.0001	1.21
Neutropenia	0.15	<.0001	1.17	0.15	<.0001	1.17
Primary hypercoagulable state	0.05	0.03	1.05	0.05	0.03	1.05
Dementia	0.18	<.0001	1.20	0.18	<.0001	1.20
Substance Related Disorders	0.11	0.001	1.12	0.11	0.001	1.11
Miscellaneous Mental Health	0.06	0.28	1.06	0.06	0.28	1.06
Opioid Dependance	0.17	<.0001	1.18	0.16	<.0001	1.18
Schizophrenia	0.11	<.0001	1.12	0.11	<.0001	1.11
Cerebral degeneration, unspecified	0.04	0.26	1.04	0.04	0.25	1.05
Peripheral autonomic neuropathy in disorders classified elsewhere	0.06	0.09	1.06	0.06	0.09	1.06
Unspecified hereditary and idiopathic peripheral neuropathy	0.03	0.02	1.03	0.03	0.02	1.03
Epilepsy	0.11	<.0001	1.12	0.11	<.0001	1.12
Bipolar Disorder	0.07	<.0001	1.07	0.06	0.0002	1.07
Major depressive affective disorder	0.10	<.0001	1.10	0.09	<.0001	1.10
Mood Disorders	0.07	0.02	1.07	0.06	0.02	1.07
Alcohol Related Disorders	0.05	0.01	1.05	0.05	0.02	1.05
Coma	0.31	<.0001	1.36	0.31	<.0001	1.36
Cerebral edema	0.25	<.0001	1.28	0.25	<.0001	1.28
Critical illness myopathy	-0.16	<.0001	0.86	-0.16	<.0001	0.86
hypertensive heart disease with heart failure	0.01	0.74	1.01	0.01	0.74	1.01

	Baseline SMR			SDS/SES Adjusted SMR		
Covariate	Coefficient	P Value	Hazard Ratio	Coefficient	P Value^	Hazard Ratio^
Myocardial Infarction	0.22	<.0001	1.25	0.22	<.0001	1.25
Coronary Atherosclerosis	0.08	<.0001	1.09	0.08	<.0001	1.09
pulmonary embolism and infarction	0.13	<.0001	1.14	0.13	<.0001	1.14
Primary pulmonary hypertension	0.11	0.02	1.12	0.11	0.02	1.12
Pulmonary Heart Disease	0.19	<.0001	1.21	0.19	<.0001	1.21
Cardiomyopathy	0.19	<.0001	1.22	0.19	<.0001	1.22
Atrioventricular block, complete	0.07	<.001	1.07	0.07	0.0003	1.07
Paroxysmal Tachycardia	0.20	<.0001	1.22	0.20	<.0001	1.22
Atrial fibrillation	0.21	<.0001	1.24	0.21	<.0001	1.24
Atrial flutter	0.05	<.0001	1.05	0.05	<.0001	1.05
Sinoatrial node dysfunction	-0.04	<.0001	0.96	-0.04	<.0001	0.96
Acute Cerebrovascular Disease	0.13	<.0001	1.14	0.13	<.0001	1.14
Peripheral and Visceral Atherosclerosis	0.15	<.0001	1.16	0.15	<.0001	1.16
Venous Thromboembolism	0.09	<.0001	1.09	0.09	<.0001	1.09
Esophageal varices	0.22	<.0001	1.25	0.23	<.0001	1.25
Chronic Obstructive Pulmonary Disease	0.13	<.0001	1.14	0.13	<.0001	1.14
Asthma	0.03	0.00	1.03	0.03	0.001	1.03
Aspiration Pneumonitis	0.12	<.0001	1.13	0.12	<.0001	1.13
Other Lower Respiratory Diseases	0.19	<.0001	1.21	0.19	<.0001	1.21
Respiratory Failure	0.18	<.0001	1.20	0.18	<.0001	1.20
Enteritis and Ulcerative Colitis	0.06	0.01	1.07	0.06	0.02	1.06
Ileus and Intestinal Obstruction	-0.01	0.36	0.99	-0.01	0.39	0.99

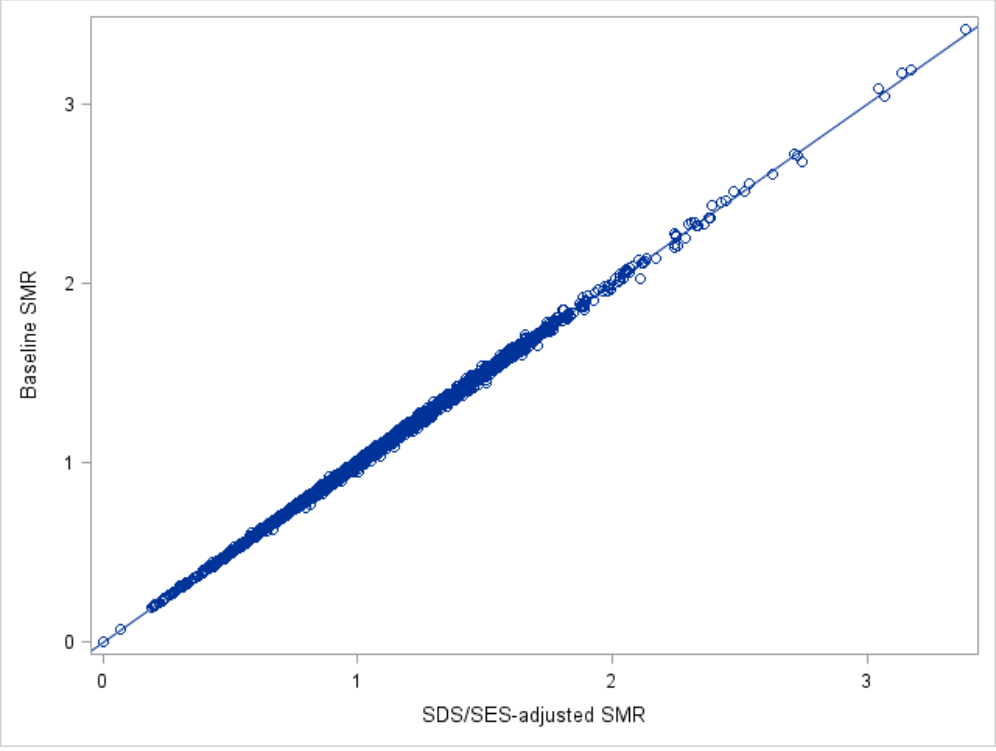
	Baseline SMR			SDS/SES Adjusted SMR		
Covariate	Coefficient	P Value	Hazard Ratio	Coefficient	P Value^	Hazard Ratio^
Cirrhosis of Liver	0.37	<.0001	1.45	0.36	<.0001	1.44
Other Liver Disease	0.27	<.0001	1.31	0.27	<.0001	1.31
Pancreatitis	0.17	<.0001	1.18	0.16	<.0001	1.18
Chronic Skin Ulcer	0.26	<.0001	1.29	0.26	<.0001	1.29
Systemic lupus erythematosus and connective tissue disorders	0.23	<.0001	1.26	0.23	<.0001	1.25
Infective arthritis and osteomyelitis	-0.12	<.0001	0.88	-0.12	<.0001	0.88
Rheumatoid Arthritis	0.08	<.0001	1.08	0.07	<.0001	1.08
Pathologic Fracture	0.16	<.0001	1.18	0.17	<.0001	1.18
Aseptic Necrosis	0.01	0.86	1.01	0.01	0.86	1.01
Hip and Femur Fracture	-0.02	0.36	0.98	-0.02	0.37	0.98
Gangrene	0.16	<.0001	1.17	0.16	<.0001	1.17
Infection due to urinary catheter	-0.002	0.92	1.00	-0.001	0.95	1.00
HIV	0.22	<.0001	1.24	0.21	<.0001	1.24
Solid Organ Transplant	0.04	0.05	1.04	0.04	0.06	1.04
Gastrostomy status	0.09	<.0001	1.09	0.09	<.0001	1.09
Ileostomy / Colostomy Status	0.01	0.41	1.01	0.01	0.42	1.01
Other artificial opening of urinary tract status	0.15	<.0001	1.16	0.15	<.0001	1.16
Dependence on respirator, status	0.05	0.03	1.05	0.05	0.03	1.05
Other toe(s) amputation status	0.02	0.15	1.02	0.02	0.17	1.02
Below knee amputation status	0.11	<.0001	1.12	0.11	<.0001	1.12
Above knee amputation status	0.14	<.0001	1.16	0.14	<.0001	1.15
Long-term (current) use of insulin	0.03	<.0001	1.03	0.03	<.0001	1.03

	Baseline SMR			SDS/SES Adjusted SMR		
Covariate	**Coefficient**	**P Value**	**Hazard Ratio**	**Coefficient**	**P Value^**	**Hazard Ratio^**
Cancer of Rectum	0.34	<.0001	1.4	0.33	<.0001	1.40
Inflammatory polyarthropathy	0.12	0.14	1.13	0.12	0.14	1.13
Sacroiliitis	-0.006	0.95	1.00	-0.01	0.95	0.99
Less than 6 Medicare covered months in prior calendar year	0.54	<.0001	1.71	0.54	<.0001	1.72

^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 black race means that the effect of female depends on race.

The figure below shows the correlation between facility SMRs with and without adjustment for patient and area-level SES.

Figure 1. Correlation between SMR with and without SES adjustment, 2015-2018



$\rho = 0.99959$

Table 6. Flagging rates, by model with and without SES adjustors: 2015-2018

		Baseline SMR		
SHR with SES	**Better than Expected**	**As Expected**	**Worse than Expected**	**Total**
Better than Expected	129	6	-	135 (2%)
As Expected	4	6,579	5	6,588(95%)
Worse than Expected	-	5	240	245 (4%)
Total	133 (2%)	6,590 (95%)	245 (4%)	6,969 (95%)

2016 Submission

These analyses indicate that some patient-level SES variables affect expected death rates, while most patient and area-level SES indicators have at most minimal effect. Furthermore, SMRs with and without adjustment for patient SES and area SES are highly correlated (0.9885, $p<0.0001$), and adjustment for SES shifts facility performance only slightly. This suggests SES does not contribute much to the flagging profiles for facility performance.

Risk adjustment for SES factors would probably reduce the likelihood of penalizing facilities serving a disproportionately larger disadvantaged patient population, resulting in lower quality performance scores and incentive payment reductions for the facility. At the same time, risk adjustment for SES may improve access to care for disadvantaged patients, by guarding against the potential providers may be otherwise less willing to take on these patients because of their higher comorbidity burden. This in effect comes with the risk of effectively holding providers to different (more relaxed) standards for expected patient outcomes, and relatedly may reduce access to the highest quality care for disadvantaged patients. Not adjusting for these sociodemographic and SES factors minimizes the likelihood of reinforcing disparities and counters the notion that different standards in care are acceptable in these populations. In the absence of definitive evidence demonstrating that socioeconomic risk adjustment does not result in differential access to care, we believe that the most appropriate decision is not to risk adjust for socioeconomic factors. Our 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 SMR model we continue to include race, ethnicity, and sex (SDS factors) for risk adjustment based on results from the literature, discussed in section 2b4.3. Patient level SES factors are not included in the final risk adjusted model. 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 SES factors and mortality, 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.

2019 Submission

After adjustment for SDS/SES, 20 facilities (0.29%) changed performance categories. 11 (0.16%) facilities were upgraded, and 9 (0.13%) were down-graded.

Patient race, Hispanic ethnicity, and female sex were associated with lower mortality however the impact of these social risk factors are conditional on their respective relationships with other risk factors captured in the interaction terms in the SMR. Among SES factors only unemployment was associated with mortality (higher risk). Neither dual eligible status or area level SES deprivation were associated with mortality. Furthermore, SMRs with and without adjustment for patient SES and area SES are highly correlated and adjustment for SES shifts facility performance only slightly. This suggests SES does not contribute much to the flagging profiles for facility performance.

Patient level SES factors are not included in the final risk adjusted model. In the absence of definitive evidence demonstrating that socioeconomic risk adjustment does not result in differential access to care, the most appropriate decision is not to risk adjust for socioeconomic factors. While other studies have shown the association between these patient and area-level SES factors and mortality, 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. 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 SMR model we continue to include race, ethnicity, and sex for risk adjustment based on results from the literature as discussed in section 2b3.3b. Specifically, the direction of the relationship between race, ethnicity and mortality is inverted relative to the general population, with lower observed mortality in blacks and Hispanics on chronic dialysis compared to whites and non-Hispanics (Kalbfleisch et al 2015). As noted by Kalbfleisch et al (2015), the intent of the measure is to clearly identify facilities whose outcomes are below the national average. With this approach, the adjusted analyses that include race, Hispanic ethnicity, and sex do not obscure disparities in health care, but tend to clarify potential disparities. Without adjustment, we may erroneously conclude that those facilities with a high concentration of these generally underserved population have outcomes better than the national norm. Females in the general population have lower mortality rates (CDC National Vital Statistics Reports, 2012) than males. Adjustment for sex allows for a fair comparison between dialysis facilities with patient populations that have a different mix of males and females.

4.5.7 Method Used to Develop the Statistical Model or Stratification Approach (NQF Testing Attachment 2b3.5.)

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.

4.5.8 Statistical Risk Model Discrimination Statistics (e.g., c-statistic, R^2) (NQF Testing Attachment 2b3.6.)

2016 Submission

In this model, the C-Statistic =0.724 which suggests good predictive ability of the risk model.

2019 Submission

In this model, the C-Statistic =0.72 which suggests good predictive ability of the risk model.

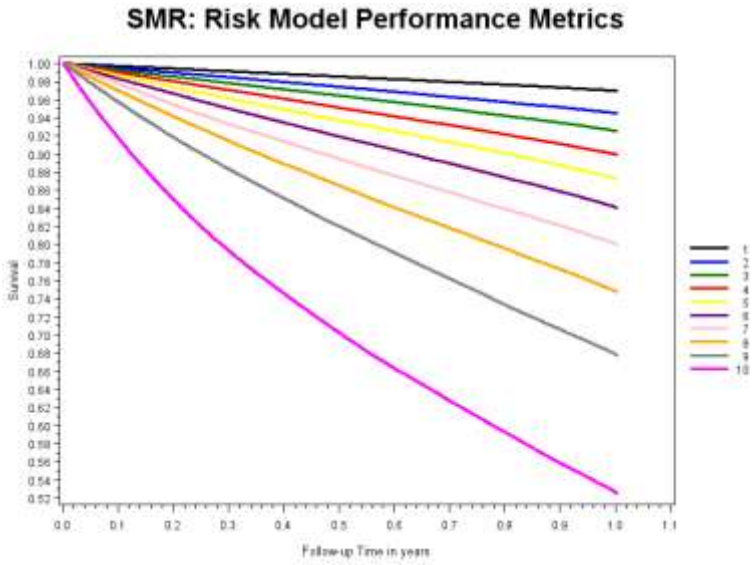
4.5.9 Statistical Risk Model Calibration Statistics (e.g., Hosmer-Lemeshow statistic) (NQF Testing Attachment 2b3.7.)

N/A

4.5.10 Statistical Risk Model Calibration—Risk decile plots or calibration curves (NQF Testing Attachment 2b3.8.)

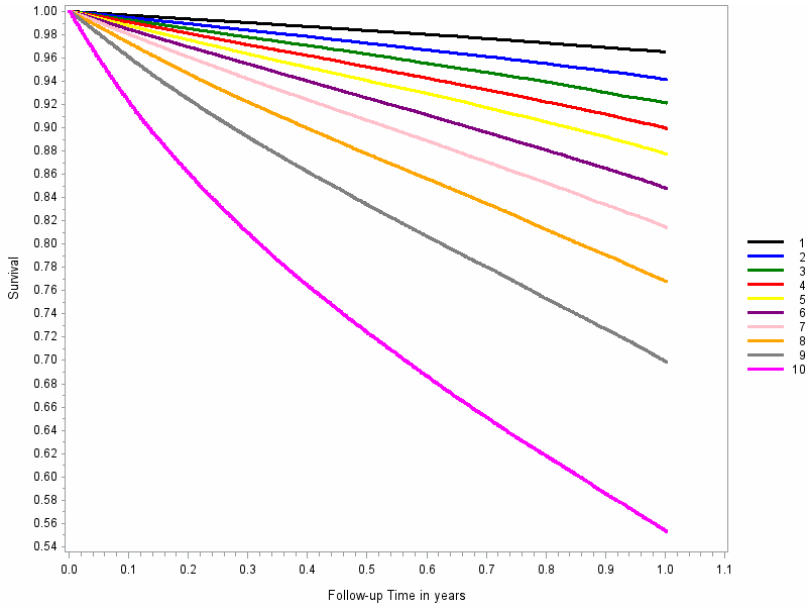
2016 Submission

Figure2. Decile plot for SMR



2019 Submission

Figure 2. Decile plot for SMR



4.5.11 Results of Risk Stratification Analysis (NQF Testing Attachment 2b3.9.)

N/A

4.5.12 Interpretation (NQF Testing Attachment 2b3.10.)

2016 Submission

Figure 2 is the decile plot showing estimates of cumulative rates by years. The 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 the best survival rates). The absolute differences between the groups is also large with survival at one year ranging from 96% for those patients predicted to have the lowest mortality rates (group 1) down to 60% for those predicted to have the lowest rates of survival (group 10).

2019 Submission

The interpretation from the previous submission remains accurate for the updated results in this submission.

4.5.13 Optional Additional Testing for Risk Adjustment (NQF Testing Attachment 2b3.11.)

N/A

4.6 Identification of Meaningful Differences in Performance **(for reference only)** (NQF Testing Attachment 2b.54.)

4.6.1 Method (NQF Testing Attachment 2b4.1.)

2016 Submission

The p-value for a given facility is a measure of the strength of the evidence against the hypothesis that the mortality rate for this facility is identical to that seen nationally overall, having adjusted for the patient mix. Thus, the p-value is the probability that the facility's SMR would deviate from 1.00 (national rate) by at least as much as the facility's observed SMR. In practice, the p-value is computed using a Poisson approximation under which the distribution of the number of deaths in the facility is Poisson with a mean value equal to E, the expected number of deaths as computed from the Cox model. Accordingly, if the observed number, O, is greater than E, then p-value = 2 * Pr(X>=O) where X has a Poisson distribution with mean E. Similarly, if O<E, the p-value = 2 * Pr(X <=O) where X has a Poisson distribution with mean E.

2019 Submission

The p-value for a given facility is a measure of the strength of the evidence against the hypothesis that the mortality rate for this facility is identical to that seen nationally overall, having adjusted for the patient mix. Thus, the p-value is the probability that the facility's SMR would deviate from 1.00 (national rate) by at least as much as the facility's observed SMR. In practice, the p-value is computed using a Poisson approximation under which the distribution of the number of deaths in the facility is Poisson with a mean value equal to E, the expected number of deaths as computed from the Cox model. Accordingly, if the observed number, O, is greater than E, then the mid p-value = Pr(X>=O)+ Pr(X>O) where X has a Poisson distribution with mean E. Similarly, if O<E, the mid p-value = Pr(X <=O)+ Pr(X<O) where X has a Poisson distribution with mean E.

To address the problem of simultaneously monitoring a large number of facilities and to take account of the intrinsic unexplained variation among facilities, we used the approach described in Kalbfleisch and Wolfe (2013). This method is based on the empirical null as described in Efron (2004, 2007). The p-value for each facility is converted to a Z-score, stratified into four groups based on patient-years within each facility. The empirical null corresponds to a normal curve that is fitted to the center of each Z-score histograms using a robust M-estimation method. The standard deviation of empirical null distribution is then used for a reference distribution (with mean 0) to identify outlier facilities. This method aims to separate underlying intrinsic variation in facility outcomes from variation that might be attributed to poor (or excellent) care.

4.6.2 Statistical Results (NQF Testing Attachment 2b4.2.)

2016 Submission

Table 6. Number and percentage of facilities by classification of the 2013 SMR. Categories stratified by facility size.

Number of patients	Better than expected	As expected	Worse than expected
<=45	0.48% (26)	21.09% (1141)	0.54% (29)
45-85	1.09% (59)	37.93% (2052)	1.50% (81)
>=86	2.03% (110)	33.48% (1811)	1.87% (101)

Table 7. Number and percentage of facilities by classification of the 2010-2013 SMR. Categories stratified by facility size.

Number of patients	Better than expected	As expected	Worse than expected
<=135	0.69% (41)	19.05% (1131)	1.18% (70)
136-305	2.21% (131)	34.38% (2041)	2.49% (148)
>=306	4.80 % (285)	31.28% (1857)	3.91% (232)

2019 Submission

Table 7. Number and percentage of facilities by classification of the 2015-2018 SMR (based on two-tailed empirical null p-value less than 5%).

Better than Expected	As Expected	Worse than Expected
133 (1.91%)	6,591 (94.58%)	245 (3.52%)

4.6.3 Interpretation (NQF Testing Attachment 2b4.3.)

2016 Submission

Facilities are flagged if they have outcomes that are extreme when compared to the variation in national death rates adjusted for patient case-mix.

For both the one-year SMR and four-year SMR, a majority of facilities had mortality that was "As Expected." Overall, for the 2013 SMR, approximately 3.6% of facilities had SMR that was "Better than expected," while 3.9% of all facilities had SMR that was "Worse than expected." Across all facilities, for the 2010-2013 SMR, approximately 7.7% of facilities had a SMR that was "Better than expected," while 7.6% of facilities had a SMR that was "Worse than expected."

2019 Submission

The effective sample size in the four-year SMR is larger than the one-year SMR. 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 mortality. 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. Across all facilities, for the 2015-2018 SMR, approximately 1.91% of facilities had a SMR that was "Better than expected," while 3.52% of facilities had a SMR that was "Worse than expected."

4.7 Comparability of Multiple Data Sources/Methods **(for reference only)** (NQF Testing Attachment 2b5.) **If multiple data sources/methods are specified, there is demonstration they produce comparable results**.

4.7.1 Method (NQF Testing Attachment 2b5.1.)

N/A

4.7.2 Statistical Results (NQF Testing Attachment 2b5.2.)

N/A

4.7.3 Interpretation (NQF Testing Attachment 2b5.3.)

N/A

4.8 Missing Data Analysis and Minimizing Bias **(for reference only)** (NQF Testing Attachment 2b6.) **.** Analyses 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.

4.8.1 Method (NQF Testing Attachment 2b6.1)

The SMR 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, SMR 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 of paid 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.

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 minimum dialysis paid 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.

4.8.2 Missing Data Analysis (NQF Testing Attachment 2b6.2)

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 SMR 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. 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 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 8) 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 8. 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)

State	N	Mean (SD)
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)
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 9. Percent Missing Data

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

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

4.8.3 Interpretation (NQF Testing Attachment 2b6.3)

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%, 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. 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 form 2728, and missing cause of ESRD. 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.

5. Feasibility (NQF Feasibility Tab)

5.1 Data Elements Generated as Byproduct of Care Processes (NQF Measure evaluation criterion 3a./3a.1)

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)

5.2 Electronic Sources (NQF Measure evaluation criterion 3b.) 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.

5.2.1 Data Elements Electronic Availability (NQF Submission Form 3b.1.)
ALL data elements are in defined fields in a combination of electronic sources

5.2.2 Path to Electronic Capture (NQF Submission Form 3b.2.)
N/A

5.2.3 eCQM Feasibility (NQF Submission Form 3b.3.)

5.3 Data Collection Strategy (NQF Measure evaluation criterion 3c.)

5.3.1 Data Collection Strategy Difficulties (optional) (NQF Submission Form 3c.1.)

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 SMR showed only rare instances of concern expressed about inaccurate or missing data.

5.3.2 Fees, Licensing, Other Requirements (NQF Submission Form 3c.2.)
N/A

6. Usability and Use (NQF Usability and Use Tab)

6.1 Use (NQF Measure evaluation criterion 4a.) 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.

6.1.1 Current and Planned Use (NQF Submission Form 4.1.)

Specific Plan for Use	**Current Use (for current use provide URL)**
	Public Reporting Dialysis Facility Compare http://www.medicare.gov/dialysisfacilitycompare/ Dialysis Facility Compare http://www.medicare.gov/dialysisfacilitycompare/

6.1.1.1 Reasons for Not Publicly Reporting or Use in Other Accountability Application (NQF Submission Form 4a.1.2.)
N/A

6.1.1.2 Plan for Implementation (NQF Submission Form 4a.1.3.)
N/A

6.1.2 Feedback on the measure by those being measured or others (NQF Measure evaluation criterion 4a2)

6.1.2.1 Technical Assistance Provided During Development or Implementation (NQF Submission Form 4a2.1.1.)

Results of this measure are currently reported on Dialysis Facility Compare. All Medicare-certified dialysis facilities are eligible for reporting. There is a helpdesk and supporting documentation available to assist with interpretation of the measure results.

6.1.2.2 Technical Assistance with Results (NQF Submission Form 4a2.1.2.)

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

6.1.2.3 Feedback on Measure Performance and Implementation (NQF Submission Form 4a2.2.1.)

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.

6.1.2.4 Feedback from Providers being Measured (NQF Submission Form 4a2.2.2.)
Comments received during DFC preview periods tend to be technical nature, asking for clarification on how the SMR is calculated for particular facilities, including questions about patient assignment and application of exclusion and risk adjustment criteria.

6.1.2.5 Feedback from Other Users (NQF Submission Form 4a2.2.3.)
N/A

6.1.2.6 Consideration of Feedback (NQF Submission Form 4a2.3.)
The revisions made to the measure specifications during this maintenance review were not directly in response to specific feedback received during public reporting (which, as described above, was more general in nature).

6.2 Usability (NQF Measure evaluation criterion 4b)

6.2.1 Improvement. (NQF Measure evaluation criterion 4b1.)

Mortality rates decreased since 2015 (reference year) as evidenced by the hazard ratios for calendar year from the SMR model. The risk of mortality for 2018 was 6% lower compared to 2015 (p-value<0.0001). The risks of mortality in 2016 and 2017 were also lower, respectively, compared to 2015 (p-value <0.0001 for each year).

2015: Reference Category
2016: Coefficient = -0.03, Hazard Ratio= 0.97, P-value = <0.0001
2017: Coefficient = -0.05, Hazard Ratio= 0.95, P-value = <0.0001
2018: Coefficient = -0.06, Hazard Ratio= 0.94, P-value = <0.0001

6.2.2 Unexpected Findings (NQF Measure evaluation criterion 4b2., NQF Submission Form 4b2.1.)
None

6.2.2.2 Unexpected Benefits (NQF Submission Form 4b2.2.)
None

7. Related and Competing Measures (NQF Related and Competing Measures Tab)

7.1 Relation to Other NQF-Endorsed Measures (NQF Measure evaluation criterion 5, NQF Submission Form 5)
Yes

7.2 Harmonization (NQF Submission Form 5a., 5a.1., 5a.2.) No
SMR is a related measure to the standardized hospitalization ratio (SHR) and the standardized readmission ratio (SRR). SMR, and SHR and SRR are harmonized to the target population they measure (Medicare-covered ESRD patients on chronic dialysis), methods (SMR and SHR) and certain risk adjustment factors specific to the ESRD population. SMR and SHR adjust for the same comorbidity risk factors, a similar set of patient characteristics, and use fixed effects in their modeling approach. The differences between SMR and SHR and SRR reflect adjustment for factors specific to the outcome of each respective measure. Both SMR and SHR adjust for a set of prevalent comorbidities (observed in a prior year), however the complete set of comorbidities for SMR differs from SRR. SRR, a measure of hospital utilization adjusts for planned readmissions; and 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 SMR. Only SMR adjusts for state death rates, race, and ethnicity to account for these respective differences related to mortality outcomes and that are deemed outside of a facility's control.

7.3 Competing Measures (NQF Submission Form 5b., 5b.1.)
N/A

NATIONAL QUALITY FORUM—Evidence (subcriterion 1a)

Measure Number (*if previously endorsed*)**:** 0369
Measure Title: Standardized Mortality 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: 4/2/2020

1a.1.This is a measure of: (*should be consistent with type of measure entered in De.1*)
Outcome
☒ Outcome: Mortality
☐ 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
The Standardized Mortality Ratio (SMR) is used by ESRD state surveyors in conjunction with other standard criteria for prioritizing and selecting facilities to survey. This patient survival classification measure is reported publicly on the DFC web site to assist patients in selecting dialysis facilities.

2016 Submission
There are numerous dialysis facility processes of care that can influence the risk of patient mortality. 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 death.
(2) Inadequate infection prevention. Inadequate infection prevention processes, including suboptimal management of vascular access, can lead to bacteremia or septicemia, increasing the possibility of death.
(3) Inadequate dialysis. Failure to maintain processes to ensure adequate dialysis can lead to low Kt/v, increasing the possibility of death.

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.)

N/A

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

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

2011 Submission

This was not a question on the 2011 Submission Form.

2016 Submission:

ESRD patients on chronic dialysis experience all cause mortality far in excess of age matched controls [1]. Patients in some dialysis facilities have consistently higher mortality than patients in other facilities, even after controlling for multiple patient characteristics [2]. Selection of dialysis modality, sometimes the result of dialysis facility practices, likely influences mortality [3]. Furthermore, mortality from certain conditions resulting from kidney failure and chronic dialysis care, including uremic toxin accumulation, volume overload/HTN and its treatment, bone/mineral disease, and infections related to dialysis access, have been described in detail [4-6].

Specific dialysis practices have been identified for several of these ESRD-related conditions that can improve patient survival and morbidity, including provision of adequate small solute clearance [7], control of total body volume while guarding against rapid ultrafiltration [8-11] and appropriate management of mineral and bone disorders [12-14]. In addition, improved infection prevention efforts by dialysis providers can result in reduced infection-related hospitalization and mortality [15-20].

2019/2020 Submission:

ESRD patients on chronic dialysis experience all-cause mortality far in excess of age matched controls in the general and Medicare populations [1]. Mortality rates across dialysis facilities vary, even after controlling for multiple patient characteristics and comorbidities [2]. Selection of dialysis modality, sometimes the result of dialysis facility practices, likely influences mortality [3]. Furthermore, mortality is associated with certain conditions resulting from kidney failure and chronic dialysis care, including uremic toxin accumulation, volume overload/HTN and its treatment, bone/mineral disease, and infections related to dialysis access, have been described in detail [4-6].

Specific dialysis practices have been identified for several of these ESRD-related conditions that can improve patient survival and morbidity, including provision of adequate small solute clearance [7], control of total body volume while guarding against rapid ultrafiltration [8-11] and appropriate management of mineral and bone disorders [12-14]. In addition, improved infection prevention efforts by dialysis providers can result in reduced infection-related hospitalization and mortality [15-20].

Additional studies have bolstered the importance of fluid management in improving patient survival [24, 26, 37]. Rescheduling missed dialysis treatments [21], as well as providing longer treatment times at dialysis initiation [33], while being mindful to preserve residual kidney function [30] all have the potential to reduce patient mortality. Nutrition counseling, and how the interdisciplinary team manages potassium [38], phosphorus [31] and encourages healthy eating habits with fruits/vegetables [39] also impact patient outcomes. Sustained efforts at influenza vaccinations can impact mortality [32]. Lastly, in the midst of a national opioid epidemic, dialysis patient are at particularly increased risk of adverse outcomes and careful attention is needed to avoid excess mortality [25].

References (all submissions, with recent references 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]. Kalbfleisch J, Wolfe R, Bell S, Sun R, Messana J, Shearon T, Ashby V, Padilla R, Zhang M, Turenne M, Pearson J, Dahlerus C, Li Y. Risk Adjustment and the Assessment of Disparities in Dialysis Mortality Outcomes. J Am Soc Nephrol. 2015; Nov;26(11):2641-5.

Abstract: Standardized mortality ratios (SMRs) reported by Medicare compare mortality at individual dialysis facilities with the national average, and are currently adjusted for race. However, whether the adjustment for race obscures or clarifies disparities in quality of care for minority groups is unknown. Cox model-based SMRs were computed with and without adjustment for patient race for 5920 facilities in the United States during 2010. The study population included virtually all patients treated with dialysis during this period. Without race adjustment, facilities with higher proportions of black patients had better survival outcomes; facilities with the highest percentage of black patients (top 10%) had overall mortality rates approximately 7% lower than expected. After adjusting for within-facility racial differences, facilities with higher proportions of black patients had poorer survival outcomes among black and non-black patients; facilities with the highest percentage of black patients (top 10%) had mortality rates approximately 6% worse than expected. In conclusion, accounting for within-facility racial differences in the computation of SMR helps to clarify disparities in quality of health care among patients with ESRD. The adjustment that accommodates within-facility comparisons is key, because it could also clarify relationships between patient characteristics and health care provider outcomes in other settings.

[3]. Weinhandl ED, Nieman KM, Gilbertson DT, Collins AJ. Hospitalization in daily home hemodialysis and matched thrice-weekly in-center hemodialysis patients. Am J Kidney Dis. 2015 Jan;65(1):98-108.

BACKGROUND: Cardiovascular disease is a common cause of hospitalization in dialysis patients. Daily hemodialysis improves some parameters of cardiovascular function, but whether it associates with lower hospitalization risk is unclear.

STUDY DESIGN: Observational cohort study using US Renal Data System data.

SETTING & PARTICIPANTS: Medicare-enrolled daily (5 or 6 sessions weekly) home hemodialysis (HHD) patients initiating NxStage System One use from January 1, 2006, through December 31, 2009, and contemporary thrice-weekly in-center hemodialysis patients, matched 5 to 1.

PREDICTOR: Daily HHD or thrice-weekly in-center hemodialysis.

OUTCOMES & MEASUREMENTS: All-cause and cause-specific hospital admissions, hospital readmissions, and hospital days assessed from Medicare Part A claims.

RESULTS: For 3,480 daily HHD and 17,400 thrice-weekly in-center hemodialysis patients in intention-to-treat analysis, the HR of all-cause admission for daily HHD versus in-center hemodialysis was 1.01 (95%CI, 0.98-1.03). Cause-specific admission HRs were 0.89 (95%CI, 0.86-0.93) for cardiovascular disease, 1.18 (95%CI, 1.13-1.23) for infection, 1.01 (95%CI, 0.93-1.09) for vascular access dysfunction, and 1.02 (95%CI, 0.99-1.06) for other morbidity. Regarding cardiovascular disease, first admission and readmission HRs for daily HHD versus in-center hemodialysis were 0.91 and 0.87, respectively. Regarding infection, first admission and readmission HRs were 1.35 and 1.03, respectively. Protective associations of daily HHD with heart failure and hypertensive disease were most pronounced, as were adverse associations of daily HHD with bacteremia/sepsis, cardiac infection, osteomyelitis, and vascular access infection.

LIMITATIONS: Results may be confounded by unmeasured factors, including vascular access type; information about dialysis frequency, duration, and dose was lacking; causes of admission may be misclassified; results may not apply to patients without Medicare coverage.

CONCLUSIONS: All-cause hospitalization risk was similar in daily HHD and thrice-weekly in-center hemodialysis patients. However, risk of cardiovascular-related admission was lower with daily HHD, and risk of infection-related admission was higher. More attention should be afforded to infection in HHD patients.

[4]. Himmelfarb J, Ikizler T. Hemodialysis N Engl J. 2010 Nov; 363:1833–1845.

Abstract: Fifty years ago, Belding Scribner and his colleagues at the University of Washington developed a blood-access device using Teflon-coated plastic tubes, which facilitated the use of repeated hemodialysis as a life-sustaining treatment for patients with uremia.1,2 The introduction of the Scribner shunt, as it became known, soon led to the development of a variety of surgical techniques for the creation of arteriovenous fistulas and grafts. Consequently, hemodialysis has made survival possible for more than a million people throughout the world who have end-stage renal disease (ESRD) with limited or no kidney function. The expansion of dialysis into a form of long-term renal-replacement therapy transformed the field of nephrology and also created a new area of medical science, which has been called the physiology of the artificial kidney. This review describes the medical, social, and economic evolution of hemodialysis therapy.

[5]. Kliger AS. Maintaining Safety in the Dialysis Facility. Clin J Am Soc Nephrol. 2015 Apr 7;10(4):688-95.

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.

[6]. Hung AM, Hakim RM. Dialysate and Serum Potassium in Hemodialysis. Am J Kidney Dis. 2015 Jul;66(1):125-32.

Abstract: Most patients with end-stage renal disease depend on intermittent hemodialysis to maintain levels of serum potassium and other electrolytes within a normal range. However, one of the challenges has been the safety of using a low-potassium dialysate to achieve that goal, given the concern about the effects that rapid and/or large changes in serum potassium concentrations may have on cardiac electrophysiology and arrhythmia. Additionally, in this patient population, there is a high prevalence of structural cardiac changes and ischemic heart disease, making them even more susceptible to acute arrhythmogenic triggers. This concern is highlighted by the knowledge that about two-thirds of all cardiac deaths in dialysis are due to sudden cardiac death and that sudden cardiac death accounts for 25% of the overall death for end-stage renal disease. Developing new approaches and practice standards for potassium removal during dialysis, as well as understanding other modifiable triggers of sudden cardiac death, such as other electrolyte components of the dialysate (magnesium and calcium), rapid ultrafiltration rates, and safety of a number of medications (ie, drugs that prolong the QT interval or use of digoxin), are critical in order to decrease the unacceptably high cardiac mortality experienced by hemodialysis-dependent patients.

[7]. Port FK, Ashby VB, Dhingra RK, Roys EC, Wolfe RA: Dialysis dose and body mass index are strongly associated with survival in hemodialysis patients. J Am Soc Nephrol 13:1061-1066, 2002

Abstract: Low dose of hemodialysis (HD) and small body size are independent risk factors for mortality. Recent changes in clinical practice, toward higher HD doses and use of more high-flux dialyzers, suggest the need to redetermine the dose level above which no benefit from higher dose can be observed. Data were analyzed from 45,967 HD patients starting end-stage renal disease (ESRD) therapy during April 1, 1997, through December 31, 1998. Data from Health Care Financing Administration (HCFA) billing records during months 10 to 15 of ESRD were used to classify each patient into one of five categories of HD dose by urea reduction ratio (URR) ranging from <60% to >75%. Cox regression models were used to calculate relative risk (RR) of mortality after adjustment for demographics, body mass index (BMI), and 18 comorbid conditions. Of the three body-size groups, the lowest BMI group had a 42% higher mortality risk than the highest BMI tertile. In each of three body-size groups by BMI, the RR was 17%, 17%, and 19% lower per 5% higher URR category among groups with small, medium, and large BMI, respectively ($P < 0.0001$ for each group). Patients treated with URR >75% had a substantially lower RR than patients treated with URR 70 to 75% ($P < 0.005$ each, for medium and small BMI groups). It is concluded that a higher dialysis dose, substantially above the Dialysis Outcomes Quality Initiative guidelines (URR >65%), is a strong predictor of lower patient mortality for patients in all body-size groups. Further reductions in mortality might be possible with increased HD dose.

[8]. Saran R, Bragg-Gresham JL, Levin NW, Twardowski ZJ, Wizemann V, Saito A, Kimata N, Gillespie BW, Combe C, Bommer J, Akiba T, Mapes DL, Young EW, Port FK. Longer Treatment Time and Slower Ultrafiltration in Hemodialysis: Associations With Reduced Mortality in the DOPPS. Kidney Int. 2006 Apr;69(7):1222-8.

Abstract: Longer treatment time (TT) and slower ultrafiltration rate (UFR) are considered advantageous for hemodialysis (HD) patients. The study included 22,000 HD patients from seven countries in the Dialysis Outcomes and Practice Patterns Study (DOPPS). Logistic regression was used to study predictors of TT > 240 min and UFR > 10 ml/h/kg bodyweight. Cox regression was used for survival analyses. Statistical adjustments were made for patient demographics, comorbidities, dose of dialysis (Kt/V), and body size. Europe and Japan had significantly longer (P < 0.0001) average TT than the US (232 and 244 min vs 211 in DOPPS I; 235 and 240 min vs 221 in DOPPS II). Kt/V increased concomitantly with TT in all three regions with the largest absolute difference observed in Japan. TT > 240 min was independently associated with significantly lower relative risk (RR) of mortality (RR = 0.81; P = 0.0005). Every 30 min longer on HD was associated with a 7% lower RR of mortality (RR = 0.93; P < 0.0001). The RR reduction with longer TT was greatest in Japan. A synergistic interaction occurred between Kt/V and TT (P = 0.007) toward mortality reduction. UFR > 10 ml/h/kg was associated with higher odds of intradialytic hypotension (odds ratio = 1.30; P = 0.045) and a higher risk of mortality (RR = 1.09; P = 0.02). Longer TT and higher Kt/V were independently as well as synergistically associated with lower mortality. Rapid UFR during HD was also associated with higher mortality risk. These results warrant a randomized clinical trial of longer dialysis sessions in thrice-weekly HD.

[9]. FHN Trial Group, Chertow GM, Levin NW, Beck GJ, Depner TA, Eggers PW, Gassman JJ, Gorodetskaya I, Greene T, James S, Larive B, Lindsay RM, Mehta RL, Miller B, Ornt DB, Rajagopalan S, Rastogi A, Rocco MV, Schiller B, Sergeyeva O, Schulman G, Ting GO, Unruh ML, Star RA, Kliger AS. In-center hemodialysis six times per week versus three times per week. N Engl J Med. 2010 Dec 9;363(24):2287-300.

BACKGROUND: In this randomized clinical trial, we aimed to determine whether increasing the frequency of in-center hemodialysis would result in beneficial changes in left ventricular mass, self-reported physical health, and other intermediate outcomes among patients undergoing maintenance hemodialysis.

METHODS: Patients were randomly assigned to undergo hemodialysis six times per week (frequent hemodialysis, 125 patients) or three times per week (conventional hemodialysis, 120 patients) for 12 months. The two coprimary composite outcomes were death or change (from baseline to 12 months) in left ventricular mass, as assessed by cardiac magnetic resonance imaging, and death or change in the physical-health composite score of the RAND 36-item health survey. Secondary outcomes included cognitive performance; self-reported depression; laboratory markers of nutrition, mineral metabolism, and anemia; blood pressure; and rates of hospitalization and of interventions related to vascular access.

RESULTS: Patients in the frequent-hemodialysis group averaged 5.2 sessions per week; the weekly standard Kt/V(urea) (the product of the urea clearance and the duration of the dialysis session normalized to the volume of distribution of urea) was significantly higher in the frequent-hemodialysis group than in the conventional-hemodialysis group (3.54±0.56 vs. 2.49±0.27). Frequent hemodialysis was associated with significant benefits with respect to both coprimary composite outcomes (hazard ratio for death or increase in left ventricular mass, 0.61; 95% confidence interval [CI], 0.46 to 0.82; hazard ratio for death or a decrease in the physical-health composite score, 0.70; 95% CI, 0.53 to 0.92). Patients randomly assigned to frequent hemodialysis were more likely to undergo interventions related to vascular access than were patients assigned to conventional hemodialysis (hazard ratio, 1.71; 95% CI, 1.08 to 2.73).

Frequent hemodialysis was associated with improved control of hypertension and hyperphosphatemia. There were no significant effects of frequent hemodialysis on cognitive performance, self-reported depression, serum albumin concentration, or use of erythropoiesis-stimulating agents.

CONCLUSIONS: Frequent hemodialysis, as compared with conventional hemodialysis, was associated with favorable results with respect to the composite outcomes of death or change in left ventricular mass and death or change in a physical-health composite score but prompted more frequent interventions related to vascular access. (Funded by the National Institute of Diabetes and Digestive and Kidney Diseases and others; ClinicalTrials.gov number, NCT00264758.).

[10]. Flythe JE, Curhan GC, Brunelli SM. Disentangling the Ultrafiltration Rate–Mortality Association: The Respective Roles of Session Length and Weight Gain. Clin J Am Soc Nephrol. 2013 Jul;8(7):1151-61

BACKGROUND AND OBJECTIVES: Rapid ultrafiltration rate is associated with increased mortality among hemodialysis patients. Ultrafiltration rates are determined by interdialytic weight gain and session length. Although both interdialytic weight gain and session length have been linked to mortality, the relationship of each to mortality, independent of the other, is not adequately defined. This study was designed to evaluate whether shorter session length independent of weight gain and larger weight gain independent of session length are associated with increased mortality.

DESIGN, SETTING, PARTICIPANTS, & MEASUREMENTS: Data were taken from a national cohort of 14,643 prevalent, thrice-weekly, in-center hemodialysis patients dialyzing from 2005 to 2009 (median survival time, 25 months) at a single dialysis organization. Patients with adequate urea clearance and delivered dialysis session ≥240 and <240 minutes were pair-matched on interdialytic weight gain (n=1794), and patients with weight gain ≤3 and >3 kg were pair-matched on session length (n=2114); mortality associations were estimated separately.

RESULTS: Compared with delivered session length ≥240, session length <240 minutes was associated with increased all-cause mortality (adjusted hazard ratio [95% confidence interval], 1.32 [1.03 to 1.69]). Compared with weight gain ≤3, weight gain >3 kg was associated with increased mortality (1.29 [1.01 to 1.65]). The associations were consistent across strata of age, sex, weight, and weight gain and session length. Secondary analyses demonstrated dose-response relationships between both and mortality.
CONCLUSIONS: Among patients with adequate urea clearance, shorter dialysis session length and greater interdialytic weight gain are associated with increased mortality; thus, both are viable targets for directed intervention.

[11]. Weiner DE, Brunelli SM, Hunt A, Schiller B, Glassrock R, Maddux FW, Johnson D, Parker T, Nissenson A. Improving clinical outcomes among hemodialysis patients: a proposal for a "volume first" approach from the chief medical officers of US dialysis providers. Am J Kidney Dis. 2014 Nov;64(5):685-95.

Abstract: Addressing fluid intake and volume control requires alignment and coordination of patients, providers, dialysis facilities, and payers, potentially necessitating a "Volume First" approach. This article reports the consensus opinions achieved at the March 2013 symposium of the Chief Medical Officers of 14 of the largest dialysis providers in the United States. These

opinions are based on broad experience among participants, but often reinforced by only observational and frequently retrospective studies, highlighting the lack of high-quality clinical trials in nephrology. Given the high morbidity and mortality rates among dialysis patients and the absence of sufficient trial data to guide most aspects of hemodialysis therapy, participants believed that immediate attempts to improve care based on quality improvement initiatives, physiologic principles, and clinical experiences are warranted until such time as rigorous clinical trial data become available. The following overarching consensus opinions emerged. (1) Extracellular fluid status should be a component of sufficient dialysis, such that approaching normalization of extracellular fluid volume should be a primary goal of dialysis care. (2) Fluid removal should be gradual and dialysis treatment duration should not routinely be less than 4 hours without justification based on individual patient factors. (3) Intradialytic sodium loading should be avoided by incorporating dialysate sodium concentrations set routinely in the range of 134-138 mEq/L, avoidance of routine use of sodium modeling, and avoidance of hypertonic saline solution. (4) Dietary counseling should emphasize sodium avoidance.

[12]. 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. Clin J Am Soc Nephrol. 2013 Dec;8(12):2132-40.

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.

[13]. Pun PH, Horton JR, Middleton JP. Dialysate calcium concentration and the risk of sudden cardiac arrest in hemodialysis patients. Clin J Am Soc Nephrol. 2013 May;8(5):797-803.

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.

[14]. 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. 2015 Jan 7;10(1):90-7.

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.

[15]. Gilbertson DT, Unruh M, McBean AM, Kausz AT, Snyder JJ, Collins AJ. Influenza vaccine delivery and effectiveness in end-stage renal disease. Kidney Int. 2003 Feb;63(2):738-43.

BACKGROUND: Influenza vaccination rates in the general population have been associated with improved outcomes, yet high-risk populations, such as end-stage renal disease (ESRD) patients, have received little attention in determining the potential benefits. This report assessed the frequency and effectiveness of influenza vaccination, while also assessing disparities in vaccination rates in the ESRD population.

METHODS: Using the United States Renal Data System research files containing claims for all Medicare ESRD patients, vaccination rates and outcomes among vaccinated and unvaccinated persons for the 1997 to 1998 and 1998 to 1999 influenza seasons were compared after adjustment for baseline demographic factors and health characteristics.

RESULTS: Vaccination rates in the ESRD population were less than 50% for each season. Influenza vaccination rates were lower in non-whites, women, younger patients, and peritoneal dialysis patients. Influenza vaccination was associated with a lower risk for hospitalization and death.

CONCLUSIONS: Despite universal coverage of free influenza vaccination, the ESRD population had a less than 50% vaccination rate for the years 1997 to 1998 and 1998 to 1999 as demonstrated by Medicare billing data. Substantial differences were found in vaccination rates among non-whites and peritoneal dialysis patients. This study confirms that the ESRD populations benefit from influenza vaccination, suggesting that dialysis providers should take advantage of all opportunities to immunize this high-risk group.

[16]. Rosenblum A, Wang W, Ball LK, Latham C, Maddux FW, Lacson E Jr. Hemodialysis catheter care strategies: a cluster-randomized quality improvement initiative. Am J Kidney Dis. 2014 Feb;63(2):259-67.

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.

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

Abstract: 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.

[18]. Dalrymple LS, Mu Y, Romano PS, Nguyen DV, Chertow GM, Delgado C, Grimes B, Kaysen GA, Johansen KL. Outcomes of infection-related hospitalization in Medicare beneficiaries receiving in-center hemodialysis. Am J Kidney Dis. 2015 May;65(5):754-62.

BACKGROUND: Infection is a common cause of hospitalization in adults receiving hemodialysis. Limited data are available about downstream events resulting from or following these hospitalizations.

STUDY DESIGN: Retrospective cohort study using the US Renal Data System.

SETTING & PARTICIPANTS: Medicare beneficiaries initiating in-center hemodialysis therapy in 2005 to 2008.

FACTORS: Demographics, dual Medicare/Medicaid eligibility, body mass index, comorbid conditions, initial vascular access type, nephrology care prior to dialysis therapy initiation, residence in a care facility, tobacco use, biochemical measures, and type of infection.

OUTCOMES: 30-day hospital readmission or death following first infection-related hospitalization.

RESULTS: 60,270 Medicare beneficiaries had at least one hospitalization for infection. Of those who survived the initial hospitalization, 15,113 (27%) were readmitted and survived the 30 days following hospital discharge, 1,624 (3%) were readmitted to the hospital and then died within 30 days of discharge, and 2,425 (4%) died without hospital readmission. Complications related to dialysis access, sepsis, and heart failure accounted for 12%, 9%, and 7% of hospital readmissions, respectively. Factors associated with higher odds of 30-day readmission or death without readmission included non-Hispanic ethnicity, lower serum albumin level, inability to ambulate or transfer, limited nephrology care prior to dialysis therapy, and specific types of infection. In comparison, older age, select comorbid conditions, and institutionalization had stronger associations with death without readmission than with readmission.

LIMITATIONS: Findings limited to Medicare beneficiaries receiving in-center hemodialysis.

CONCLUSIONS: Hospitalizations for infection among patients receiving in-center hemodialysis are associated with exceptionally high rates of 30-day hospital readmission and death without readmission.

[19]. 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.

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.

[20]. Gilbertson DT, Wetmore JB. Infections Requiring Hospitalization in Patients on Hemodialysis. Clin J Am Soc Nephrol. 2015 Dec 7;10(12):2101-3.

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%.

[21] Dena E. Cohen, Kathryn S. Gray, Carey Colson, David B. Van Wyck, Francesca Tentori, and Steven M. Brunelli. Impact of Rescheduling a Missed Hemodialysis Treatment on Clinical Outcomes. Kidney Medicine. Volume 2, Issue 1, January–February 2020, Pages 12-19

Rationale & Objective: Among patients treated with in-center hemodialysis (HD), missed treatments are associated with higher subsequent rates of hospitalization and other adverse outcomes compared with attending treatment. The objective of this study was to determine whether and to what degree attending a rescheduled treatment on the day following a missed treatment ameliorates these risks.
Study Design: Retrospective, observational.
Setting & Participants: Included patients were those who were, as of any of 12 index dates during 2014, adult Medicare beneficiaries treated with in-center HD (vintage ≥ 90 days) on a Monday/Wednesday/Friday schedule.
Exposure: Treatment attendance on the index date and the subsequent day.
Outcomes: Hospital admissions, emergency department visits, mortality, blood pressure, and anemia measures, considered during the 7- and 30-day periods following exposure.
Analytical Approach: In parallel analyses, patients who missed or rescheduled treatment were each matched (1:5) to patients who attended treatment on the index date on the basis of index day of week and propensity score. Within the matched cohorts, outcomes were compared across exposures using repeated-measures generalized linear models.
Results: Compared with attending treatment (N = 19,260), a missed treatment (N = 3,852) was associated with a 2.09-fold higher rate of hospitalization in the subsequent 7 days; a rescheduled treatment (N = 2,128) was associated with a 1.68-fold higher rate of hospitalization than attending (N = 10,640). Compared with attending treatment, hospitalization rates were 1.39- and 1.28-fold higher among patients who missed and rescheduled treatment, respectively, during the 30-day outcome period. Emergency department visits followed a similar pattern of associations as hospitalization. No statistically significant associations were observed with respect to mortality for either missed or rescheduled treatments compared with attending treatment.
Limitations: Possible influence of unmeasured confounding; unknown generalizability to patients with non-Medicare insurance.
Conclusions: Attending a rescheduled in-center HD treatment attenuates but does not fully mitigate the adverse effects of a missed treatment.

[22] Abdulkareem Agunbiade , Abhijit Dasgupta , Michael M Ward. Racial/Ethnic Differences in Dialysis Discontinuation and Survival After Hospitalization for Serious Conditions Among Patients on Maintenance Dialysis. J Am Soc Nephrol, 31 (1), 149-160 Jan 2020.

Background: Racial and ethnic minorities on dialysis survive longer than whites, and are less likely to discontinue dialysis. Both differences have been attributed by some clinicians to better health among minorities on dialysis.
Methods: To test if racial and ethnic differences in dialysis discontinuation reflected better health, we conducted a retrospective cohort study of survival and dialysis discontinuation among patients on maintenance dialysis in the US Renal Data System after hospitalization for either stroke (n=60,734), lung cancer (n=4100), dementia (n=40,084), or failure to thrive (n=42,950) between 2003 and 2014. We examined the frequency of discontinuation of dialysis and used simulations to estimate survival in minorities relative to whites if minorities had the same pattern of dialysis discontinuation as whites.
Results: Blacks, Hispanics, and Asians had substantially lower frequencies of dialysis discontinuation than whites in each hospitalization cohort. Observed risks of mortality were also lower for blacks, Hispanics, and Asians. In simulations that assigned discontinuation patterns similar to those found among whites across racial and ethnic groups, differences in survival were markedly attenuated and hazard ratios approached 1.0. Survival and dialysis discontinuation frequencies among American Indians and Alaska Natives were close to those of whites.
Conclusions: Racial and ethnic differences in dialysis discontinuation were present among patients hospitalized with similar health events. Among these patients, survival differences between racial and ethnic minorities and whites were largely attributable to differences in the frequency of discontinuation of dialysis.

[23] Fozia Ajmal, Janice C Probst, John M Brooks, James W Hardin, Zaina Qureshi, Tazeen H Jafar . Freestanding Dialysis Facility Quality Incentive Program Scores and Mortality Among Incident Dialysis Patients in the United States. Am J Kidney Dis, 75 (2), 177-186 Feb 2020.

Rationale & objective: The Centers for Medicare & Medicaid Services introduced the Quality Incentive Program (QIP) along with the bundled payment reform to improve the quality of dialysis care in the United States. The QIP has been criticized for using easily obtained laboratory indicators without patient-centered measures and for a lack of evidence for an association between QIP indicators and patient outcomes. This study examined the association between dialysis facility QIP performance scores and survival among patients after initiation of dialysis.
Study design: Retrospective cohort study.
Setting & participants: Study participants included 84,493 patients represented in the US Renal Disease System's patient-level data who had initiated dialysis between January 1, 2013, and December 1, 2013, and who did not, during the first 90 days after dialysis initiation, die, receive a transplant, or become lost to follow-up. Patients were followed up for the study outcome through March 31, 2014.
Predictor: Dialysis facility QIP scores.
Outcome: Mortality.
Analytical approach: Using a unique facility identifier, we linked Medicare freestanding dialysis facility data from 2015 with US Renal Disease System patient-level data. Kaplan-Meier product limit estimator was used to describe the survival of study participants. Cox proportional hazards

regression was used to assess the multivariable association between facility performance scores and patient survival.
Results: Excluding patients who died during the first 90 days of dialysis, 11.8% of patients died during an average follow-up of 5 months. Facilities with QIP scores<45 (HR, 1.39; 95% CI, 1.15-1.68) and 45 to<60 (HR, 1.21; 95% CI, 1.10-1.33) had higher patient mortality rates than facilities with scores≥90.
Limitations: Because the Centers for Medicare & Medicaid Services have revised QIP criteria each year, the findings may not relate to years other than those studied.
Conclusions: Dialysis facilities characterized by lower QIP scores were associated with higher rates of patient mortality. These findings need to be replicated to assess their consistency over time.

[24] Magdalene M Assimon, Julia B Wenger, Lily Wang, Jennifer E Flythe. Ultrafiltration Rate and Mortality in Maintenance Hemodialysis Patients. Am J Kidney Dis, 68 (6), 911-922 Dec 2016.

Background: Observational data have demonstrated an association between higher ultrafiltration rates and greater mortality among hemodialysis patients. Prior studies were small and did not consider potential differences in the association across body sizes and other related subgroups. No study has investigated ultrafiltration rates normalized to anthropometric measures beyond body weight. Also, potential methodological shortcomings in prior studies have led to questions about the veracity of the ultrafiltration rate-mortality association.
Study design: Retrospective cohort.
Setting & participants: 118,394 hemodialysis patients dialyzing in a large dialysis organization, 2008 to 2012.
Predictors: Mean 30-day ultrafiltration rates were dichotomized at 13 and 10mL/h/kg, separately and categorized using various cutoff points. Ultrafiltration rates normalized to body weight, body mass index, and body surface area were investigated.
Outcomes: All-cause mortality.
Measurements: Multivariable survival models were used to estimate the association between ultrafiltration rate and all-cause mortality.
Results: At baseline, 21,735 (18.4%) individuals had ultrafiltration rates > 13mL/h/kg and 48,529 (41.0%) had ultrafiltration rates > 10mL/h/kg. Median follow-up was 2.3 years, and the mortality rate was 15.3 deaths/100 patient-years. Compared with ultrafiltration rates ≤ 13mL/h/kg, ultrafiltration rates > 13mL/h/kg were associated with greater mortality (adjusted HR, 1.31; 95% CI, 1.28-1.34). Compared with ultrafiltration rates ≤ 10mL/h/kg, ultrafiltration rates > 10mL/h/kg were associated with greater mortality (adjusted HR, 1.22; 95% CI, 1.20-1.24). Findings were consistent across subgroups of sex, race, dialysis vintage, session duration, and body size. Higher ultrafiltration rates were associated with greater mortality when normalized to body weight, body mass index, and body surface area.
Limitations: Residual confounding cannot be excluded given the observational study design.
Conclusions: Regardless of the threshold implemented, higher ultrafiltration rate was associated with greater mortality in the overall study population and across key subgroups. Randomized controlled trials are needed to investigate whether ultrafiltration rate reduction improves clinical outcomes.

[25] Kimmel PL, Fwu CW, Abbott KC, Eggers AW, Kline PP, Eggers PW. J Am Soc Nephrol. 2017 Dec;28(12):3658-3670. doi: 10.1681/ASN.2017010098. Epub 2017 Sep 21. Opioid Prescription, Morbidity, and Mortality in United States Dialysis Patients.

Aggressive pain treatment was advocated for ESRD patients, but new Centers for Disease Control and Prevention guidelines recommend cautious opioid prescription. Little is known regarding outcomes associated with ESRD opioid prescription. We assessed opioid prescriptions and associations between opioid prescription and dose and patient outcomes using 2006-2010 US Renal Data System information in patients on maintenance dialysis with Medicare Part A, B, and D coverage in each study year (n=671,281, of whom 271,285 were unique patients). Opioid prescription was confirmed from Part D prescription claims. In the 2010 prevalent cohort (n=153,758), we examined associations of opioid prescription with subsequent all-cause death, dialysis discontinuation, and hospitalization controlled for demographics, comorbidity, modality, and residence. Overall, >60% of dialysis patients had at least one opioid prescription every year. Approximately 20% of patients had a chronic (≥90-day supply) opioid prescription each year, in 2010 usually for hydrocodone, oxycodone, or tramadol. In the 2010 cohort, compared with patients without an opioid prescription, patients with short-term (1-89 days) and chronic opioid prescriptions had increased mortality, dialysis discontinuation, and hospitalization. All opioid drugs associated with mortality; most associated with worsened morbidity. Higher opioid doses correlated with death in a monotonically increasing fashion. We conclude that opioid drug prescription is associated with increased risk of death, dialysis discontinuation, and hospitalization in dialysis patients. Causal relationships cannot be inferred, and opioid prescription may be an illness marker. Efforts to treat pain effectively in patients on dialysis yet decrease opioid prescriptions and dose deserve consideration.

[26] Zoccali C, Moissl U, Chazot C, Mallamaci F, Tripepi G, Arkossy O, Wabel P, Stuard S. J Am Soc Nephrol. 2017 Aug;28(8):2491-2497. doi: 10.1681/ASN.2016121341. Epub 2017 May 4. Chronic Fluid Overload and Mortality in ESRD.

Sustained fluid overload (FO) is considered a major cause of hypertension, heart failure, and mortality in patients with ESRD on maintenance hemodialysis. However, there has not been a cohort study investigating the relationship between chronic exposure to FO and mortality in this population. We studied the relationship of baseline and cumulative FO exposure over 1 year with mortality in 39,566 patients with incident ESRD in a large dialysis network in 26 countries using whole-body bioimpedance spectroscopy to assess fluid status. Analyses were applied across three discrete systolic BP (syst-BP) categories (<130, 130-160, and >160 mmHg), with nonoverhydrated patients with syst-BP=130-160 mmHg as the reference category; >200,000 FO measurements were performed over follow-up. Baseline FO value predicted excess risk of mortality across syst-BP categories (<130 mmHg: hazard ratio [HR], 1.51; 95% confidence interval [95% CI], 1.38 to 1.65; 130-160 mmHg: HR, 1.25; 95% CI, 1.16 to 1.36; >160 mmHg: HR, 1.30; 95% CI, 1.19 to 1.42; all P<0.001). However, cumulative 1-year FO exposure predicted a higher death risk (P<0.001) across all syst-BP categories (<130 mmHg: HR, 1.94; 95% CI, 1.68 to 2.23; 130-160 mmHg: HR, 1.51; 95% CI, 1.35 to 1.69; >160 mmHg: HR, 1.62; 95% CI, 1.39 to 1.90). In conclusion, chronic exposure to FO in ESRD is a strong risk factor for death across discrete BP categories. Whether treatment policies that account for fluid status monitoring are preferable to policies that account solely for predialysis BP measurements remains to be tested in a clinical trial.

[27] Ku E, Yang W, McCulloch CE, Feldman HI, Go AS, Lash J, Bansal N, He J, Horwitz E, Ricardo AC, Shafi T, Sondheimer J, Townsend RR, Waikar SS, Hsu CY; Am J Kidney Dis. 2019 Nov 12:S0272-6386(19)30974-6. doi: 10.1053/j.ajkd.2019.08.011. Online ahead of print. Race and Mortality in CKD and Dialysis:

Findings From the Chronic Renal Insufficiency Cohort (CRIC) Study. CRIC Study Investigators. Collaborators: Appel LJ, Kusek JW, Rao PS, Rahman M.

RATIONALE & OBJECTIVES: Few studies have investigated racial disparities in survival among dialysis patients in a manner that considers risk factors and mortality during the phase of kidney disease before maintenance dialysis. Our objective was to explore racial variations in survival among dialysis patients and relate them to racial differences in comorbid conditions and rates of death in the setting of kidney disease not yet requiring dialysis therapy.
STUDY DESIGN: Retrospective cohort study.
SETTINGS & PARTICIPANTS: 3,288 black and white participants in the Chronic Renal Insufficiency Cohort (CRIC), none of whom were receiving dialysis at enrollment.
EXPOSURE: Race.
OUTCOME: Mortality.
ANALYTIC APPROACH: Cox proportional hazards regression was used to examine the association between race and mortality starting at: (1) time of dialysis initiation and (2) entry into the CRIC.
RESULTS: During 7.1 years of median follow-up, 678 CRIC participants started dialysis. Starting from the time of dialysis initiation, blacks had lower risk for death (unadjusted HR, 0.67; 95% CI, 0.51-0.87) compared with whites. Starting from baseline CRIC enrollment, the strength of the association between some risk factors and dialysis was notably stronger for whites than blacks. For example, the HR for dialysis onset in the presence (vs absence) of heart failure at CRIC enrollment was 1.30 (95% CI, 1.01-1.68) for blacks versus 2.78 (95% CI, 1.90-4.50) for whites, suggesting differential severity of these risk factors by race. When we included deaths occurring both before and after dialysis, risk for death was higher among blacks (vs whites) starting from CRIC enrollment (HR, 1.41; 95% CI, 1.22-1.64), but this finding was attenuated in adjusted models (HR, 1.08; 95% CI, 0.91-1.28).
LIMITATIONS: Residual confounding.
CONCLUSIONS: The apparent survival advantage among blacks over whites treated with dialysis may be attributed to selected transition of a subset of whites with more severe comorbid conditions onto dialysis.

[28] Am J Nephrol. 2019;49(3):241-253. doi: 10.1159/000497446. Epub 2019 Feb 28.
Temporal Trends in Incident Mortality in Dialysis Patients: Focus on Sex and Racial Disparities.
Shah S, Leonard AC, Meganathan K, Christianson AL, Thakar CV.

BACKGROUND: Racial minorities and women constitute substantial portions of the incident and prevalent end-stage renal disease (ESRD) population in the United States. Although ESRD is characterized by high mortality, temporal trends, and race and sex differences in mortality have not been studied. METHODS: We evaluated 944,650 adult patients who initiated dialysis between January 1, 2005 and December 31, 2014, using the United States Renal Data System, for sex-related and race-related trends in mortality. Logistic regression models adjusted for pre-dialysis health status were used to examine associations among the predictors' sex, race, and year of incident dialysis, and the outcome all-cause mortality at 1-year post ESRD. RESULTS: The mean age was 65 ± 14 years. The 1-year crude mortality rates in incident ESRD patients decreased by 28% from 2004 to 2015. Risk-adjusted 1-year mortality decreased by 3% for each later year of incident ESRD ($p < 0.001$). In general, from 2005 to 2014, mortality rates decreased across both sexes, and all races. White patients experienced the lowest reduction in adjusted 1-year mortality rates (16%). While women experienced a survival advantage over men in 2005, by 2014 it was reversed to survival advantage for men. Combining all years, the adjusted risk of

dying at 1-year after initiating dialysis was lower in women than men (OR 0.98; 95% CI 0.97-0.99), and as compared to whites, was lower in blacks (OR 0.73; 95% CI -0.72-0.74), Hispanics (OR 0.64; 95% CI 0.63-0.65), Asians (OR 0.55; 95% CI 0.53-0.56), and Native Americans (OR 0.67; 95% CI 0.63-0.71). CONCLUSION: The 1-year mortality rates among patients with ESRD have decreased steadily during a recent 10-year period across both men and women, and in all 5 races. Women have only a 2% lower risk of dying at 1-year after dialysis initiation than men. White patients had higher mortality as compared to other races. Our results suggest the need for sex, and race-specific treatment strategies in ESRD care.

[29] Bowman B, Zheng S, Yang A, Schiller B, Morfín JA, Seek M, Lockridge RS.
Am J Kidney Dis. 2018 Aug;72(2):278-283. doi: 10.1053/j.ajkd.2018.01.035. Epub 2018 Mar 3.
Improving Incident ESRD Care Via a Transitional Care Unit.

Dialysis care in the United States continues to move toward an emphasis on continuous quality improvement and performance benchmarking. Government- and industry-sponsored programs have evolved to assess and incentivize outcomes for many components of end-stage renal disease care. One aspect that remains largely unaddressed at a systemic level is the high-risk transition period from chronic kidney disease and acute kidney injury to permanent dialysis dependence. Incident dialysis patients experience disproportionately high mortality and hospitalization rates coupled with high costs. This article reviews the clinical case for a special emphasis on this transition period, reviews published literature regarding prior transitional care programs, and proposes a novel iteration of the first 30 days of dialysis care: the transitional care unit (TCU). The goal of a TCU is to improve awareness of all aspects of renal replacement therapy, including modalities, access, transplantation options, and nutritional and psychosocial aspects of the disease. This enables patients to make truly informed decisions regarding their care. The TCU model is open to all patients, including incident patients with end-stage renal disease, those for whom peritoneal dialysis is failing, or those with failing transplants. This model may be especially beneficial to those who are deemed inadequately prepared or "crash start" patients.

[30] Li T, Wilcox CS, Lipkowitz MS, Gordon-Cappitelli J, Dragoi S.
Am J Nephrol. 2019;50(6):411-421. doi: 10.1159/000503805. Epub 2019 Oct 18.
Rationale and Strategies for Preserving Residual Kidney Function in Dialysis Patients.

BACKGROUND: Residual kidney function (RKF) conveys a survival benefit among dialysis patients, but the mechanism remains unclear. Improved volume control, clearance of protein-bound and middle molecules, reduced inflammation and preserved erythropoietin and vitamin D production are among the proposed mechanisms. Preservation of RKF requires techniques to measure it accurately to be able to uncover factors that accelerate its loss and interventions that preserve it and ultimately to individualize therapy. The average of renal creatinine and urea clearance provides a superior estimate of RKF in dialysis patients, when compared with daily urine volume. However, both involve the difficult task of obtaining an accurate 24-h urine sample. SUMMARY: In this article, we first review the definition and measurement of RKF, including newly proposed markers such as serum levels of beta2-microglobulin, cystatin C and beta-trace protein. We then discuss the predictors of RKF loss in new dialysis patients. We review several strategies to preserve RKF such as renin-angiotensin-aldosterone system blockade, incremental dialysis, use of biocompatible membranes and ultrapure dialysate in hemodialysis (HD) patients, and use of biocompatible solutions in peritoneal dialysis (PD)

patients. Despite their generally adverse effects on renal function, aminoglycoside antibiotics have not been shown to have adverse effects on RKF in well-hydrated patients with end-stage renal disease (ESRD). Presently, the roles of better blood pressure control, diuretic usage, diet, and dialysis modality on RKF remain to be clearly established. Key Messages: RKF is an important and favorable prognostic indicator of reduced morbidity, mortality, and higher quality of life in both PD an HD patients. Further investigation is warranted to uncover factors that protect or impair RKF. This should lead to improved quality of life and prolonged lifespan in patients with ESRD and cost-reduction through patient centeredness, individualized therapy, and precision medicine approaches.

[31] Hou Y, Li X, Sun L, Qu Z, Jiang L, Du Y. Clin Chim Acta. 2017 Nov;474:108-113. doi: 10.1016/j.cca.2017.09.005. Epub 2017 Sep 10. Phosphorus and mortality risk in end-stage renal disease: A meta-analysis.

BACKGROUND: Studies on the association of abnormal serum phosphorus level with all-cause mortality in patients with end-stage renal disease (ESRD) have yielded inconsistent results.
OBJECTIVE: To evaluate the association of abnormal serum phosphorus level with all-cause mortality in patients with ESRD requiring dialysis by conducting a meta-analysis.
METHODS: Pubmed and Embase databases were searched through March 2017 to identify all observational studies that assessed the association between abnormal serum phosphorus level and all-cause mortality risk in patients with ESRD requiring dialysis. Pooled hazard risk (HR) with 95% confidence interval (CI) was calculated for the highest versus referent phosphorus category and lower versus referent phosphorus category, separately.
RESULTS: Nine cohort studies were eligible for analysis. During 12 to 97.6months follow-up duration, 24,463 death events occurred among 1,992,869 ESRD patients. Meta-analysis showed that the pooled HR of all-cause mortality was 1.16 (95% CI 1.06-1.28) for the lower versus referent serum phosphorus category. Similarly, patients with highest serum phosphorus levels were associated with an increased risk of all-cause mortality (HR 1.39; 95% CI 1.31-1.47) compared with those in the referent phosphorus category. Subgroup analyses revealed that the effect of phosphorus on the all-cause mortality risk appeared to be stronger within 2years follow-up.
CONCLUSIONS: Both very high and very low values of phosphorus are independently associated with an increased risk for all-cause mortality in ESRD patients requiring dialysis. This meta-analysis highlighted a non-linear association of serum phosphorus with all-cause mortality among dialysis-dependent ESRD patients.

[32] Gilbertson DT, Rothman KJ, Chertow GM, Bradbury BD, Brookhart MA, Liu J, Winkelmayer WC, Stürmer T, Monda KL, Herzog CA, Ashfaq A, Collins AJ, Wetmore JB.
J Am Soc Nephrol. 2019 Feb;30(2):346-353. doi: 10.1681/ASN.2018060581. Epub 2019 Jan 24.
Excess Deaths Attributable to Influenza-Like Illness in the ESRD Population.

BACKGROUND: Morbidity and mortality vary seasonally. Timing and severity of influenza seasons contribute to those patterns, especially among vulnerable populations such as patients with ESRD. However, the extent to which influenza-like illness (ILI), a syndrome comprising a range of potentially serious respiratory tract infections, contributes to mortality in patients with ESRD has not been quantified.
METHODS: We used data from the Centers for Disease Control and Prevention (CDC) Outpatient Influenza-like Illness Surveillance Network and Centers for Medicare and Medicaid Services ESRD

death data from 2000 to 2013. After addressing the increasing trend in deaths due to the growing prevalent ESRD population, we
calculated quarterly relative mortality compared with average third-quarter (summer) death counts. We used linear regression models to assess the relationship between ILI data and mortality, separately for quarters 4 and 1 for each influenza season, and model parameter estimates to predict seasonal mortality counts and calculate excess ILI-associated deaths.
RESULTS: An estimated 1% absolute increase in quarterly ILI was associated with a 1.5% increase in relative mortality for quarter 4 and a 2.0% increase for quarter 1. The average number of annual deaths potentially attributable to ILI was substantial, about 1100 deaths per year.
CONCLUSIONS: We found an association between community ILI activity and seasonal variation in all-cause mortality in patients with ESRD, with ILI likely contributing to >1000 deaths annually. Surveillance efforts, such as timely reporting to the CDC of ILI activity within dialysis units during influenza season, may help focus attention on high-risk periods for this vulnerable population.

[33] Swaminathan S, Mor V, Mehrotra R, Trivedi AN. Am J Kidney Dis. 2017 Jul;70(1):69-75. doi: 10.1053/j.ajkd.2016.11.017. Epub 2017 Feb 21. Initial Session Duration and Mortality Among Incident Hemodialysis Patients.

BACKGROUND: The association of dialysis session duration with mortality in patients undergoing maintenance hemodialysis is unclear. We compared mortality rates of patients treated in dialysis facilities that used initial session durations of either ≥ 4 versus 3 hours for all incident patients.
STUDY DESIGN: Retrospective cohort study.
SETTINGS & PARTICIPANTS: Patients with end-stage renal disease beginning maintenance hemodialysis therapy in January 2006 to December 2010 and followed up through December 2012, including 39,172 patients in 852 facilities who initiated treatment for ≥ 4 hours and 47,721 patients in 631 facilities who initiated treatment for 3 hours.
PREDICTOR: Initial session duration of ≥ 4 hours versus 3 hours.
OUTCOME: 2- and 1-year mortality rates.
RESULTS: Total numbers of deaths observed within 2 years after initiating dialysis therapy were 8,945 in the ≥ 4-hour group and 15,624 in the 3-hour group. The corresponding numbers of deaths observed within 1 year were 5,492 and 10,372, respectively. The 2-year adjusted HR in the ≥ 4-hour versus 3-hour group was 0.79 (95% CI, 0.73-0.86). The corresponding 1-year sdjusted HR was 0.77 (95% CI, 0.70-0.84). Results were robust when analyses were restricted to specific subgroups of patients classified by age, sex, race, and select clinical characteristics.
LIMITATIONS: We did not observe hemodialysis duration in sessions subsequent to initiation. We only included patients treated in facilities with uniform session length (at initiation) for all their patients. Furthermore, we lacked information for dialysis dosage and patients' baseline residual kidney function.
CONCLUSIONS: Patients in facilities routinely initiating hemodialysis therapy for ≥ 4 hours may have substantially lower mortality as compared with patients in facilities initiating for only 3 hours of treatment.

[34] Schold JD, Flechner SM(, Poggio ED, Augustine JJ, Goldfarb DA, Sedor JR, Buccini LD .Am J Kidney Dis. 2018 Jul;72(1):19-29. doi: 10.1053/j.ajkd.2017.12.014. Epub 2018 Mar 7. Residential Area Life Expectancy: Association With Outcomes and Processes of
Care for Patients With ESRD in the United States. Comment in Am J Kidney Dis. 2018 Jul;72(1):4-6.

BACKGROUND: The effects of underlying noncodified risks are unclear on the prognosis of patients with end-stage renal disease (ESRD). We aimed to evaluate the association of residential area life expectancy with outcomes and processes of care for patients with ESRD in the United States.
STUDY DESIGN: Retrospective cohort study.
SETTING & PARTICIPANTS: Adult patients with incident ESRD between 2006 and 2013 recorded in the US Renal Data System (n=606,046).
PREDICTOR: The primary exposure was life expectancy in the patient's residential county estimated by the Institute for Health Metrics and Evaluation.
OUTCOMES: Death, placement on the kidney transplant wait list, living and deceased donor kidney transplantation, and posttransplantation graft loss.
RESULTS: Median life expectancies of patients' residences were 75.6 (males) and 80.4 years (females). Compared to the highest life expectancy quintile and adjusted for demographic factors, disease cause, and multiple comorbid conditions, the lowest quintile had adjusted HRs for mortality of 1.20 (95% CI,
1.18-1.22); placement onto the waiting list, 0.68 (95% CI, 0.67-0.70); living donor transplantation, 0.53 (95% CI, 0.51-0.56); posttransplantation graft loss, 1.35 (95% CI, 1.27-1.43); and posttransplantation mortality, 1.29 (95% CI, 1.19-1.39). Patients living in areas with lower life expectancy were less likely
to be informed about transplantation, be under the care of a nephrologist, or receive an arteriovenous fistula as the initial dialysis access. Results remained consistent with additional adjustment for zip code-level median income, population size, and urban-rural locality.
LIMITATIONS: Potential residual confounding and attribution of effects to individuals based on residential area-level data.
CONCLUSIONS: Residential area life expectancy, a proxy for socioeconomic, environmental, genetic, and behavioral factors, was independently associated with mortality and process-of-care measures for patients with ESRD. These results emphasize the underlying effect on health outcomes of the environment in which patients live, independent of patient-level factors. These findings may have implications for provider assessments.

[35] BMC Nephrol. 2019 Jul 29;20(1):285. doi: 10.1186/s12882-019-1473-0. Long-term outcomes among Medicare patients readmitted in the first year of hemodialysis: a retrospective cohort study.
Ross KH, Jaar BG, Lea JP, Masud T, Patzer RE, Plantinga LC.

BACKGROUND: Readmission within 30 days of hospital discharge is common and costly among end-stage renal disease (ESRD) patients. Little is known about long-term outcomes after readmission. We estimated the association between hospital admissions and readmissions in the first year of dialysis and outcomes in the second year.
METHODS: Data on incident dialysis patients with Medicare coverage were obtained from the United States Renal Data System (USRDS). Readmission patterns were summarized as no admissions in the first year of dialysis (Admit-), at least one admission but no readmissions within 30 days (Admit+/Readmit-), and admissions with at least one readmission within 30 days (Admit+/Readmit+).We used Cox proportional hazards models to estimate the association between readmission pattern and mortality, hospitalization, and kidney transplantation, accounting for demographic and clinical covariates.
RESULTS: Among the 128,593 Medicare ESRD patients included in the study, 18.5% were Admit+/Readmit+, 30.5% were Admit+/Readmit-, and 51.0% were Admit-. Readmit+/Admit+ patients had substantially higher long-term risk of mortality (HR = 3.32 (95% CI, 3.21-3.44)),

hospitalization (HR = 4.46 (95% CI, 4.36-4.56)), and lower likelihood of kidney transplantation (HR = 0.52 (95% CI, 0.44-0.62)) compared to Admit- patients; these associations were stronger than those among Admit+/Readmit- patients.
CONCLUSIONS: Patients with readmissions in the first year of dialysis were at substantially higher risk of poor outcomes than either patients who had no admissions or patients who had hospital admissions but no readmissions. Identifying strategies to both prevent readmission and mitigate risk among patients who had a readmission may improve outcomes among this substantial, high-risk group of ESRD patients.

[36] Clin Nephrol. 2016 Nov;86 (2016)(11):262-269. doi: 10.5414/CN108816.
Data completeness as an unmeasured confounder in dialysis facility performance comparison with 1-year follow-up. Liu J, Krishnan M, Zhou J, Nieman KM, Peng Y, Gilbertson DT.

Aims: Standardized mortality and hospitalization ratios (SMRs, SHRs) are used to measure dialysis facility performance in the US, with adjustment for demographics and comorbid conditions derived from the end-stage renal disease (ESRD) Medical Evidence (ME) Report. Sensitivities are low for ME-based comorbidity, and levels of under-reporting may differ among facilities. We aimed to assess the effect of data inaccuracy on performance comparison.
METHODS: Using the United States Renal Data System ESRD database, we included patients who initiated hemodialysis July 1 - December 31 in each of the years 2006 - 2010, had Medicare as primary payer, were aged ≥ 66 years, and had no prior transplant. Patients were followed from dialysis initiation to the earliest of death, transplant, modality change, or 1 year. SMRs and SHRs were calculated for for-profit/non-profit and rural/urban facilities for ME-based and claims-based comorbidity, separately. Cox models were used for expected number of deaths and piecewise Poison models for expected number of hospitalizations. Comorbidity agreement was measured by κ-statistic. Testing of differences between ME-based and claims-based SMRs/SHRs was performed by bootstrap.
RESULTS: In all, 73,950 incident hemodialysis patients were included. κ-values for comorbidity agreement were low, < 0.5, except for diabetes (0.77). Percentages of claims-based comorbidity were similar for for-profit and non-profit facilities; ME-based comorbidity was lower for for-profit facilities. Differences between ME-based and claims-based SMRs/SHRs were statistically significant. Compared with ME-based SMRs/SHRs, claims-based ratios decreased 0.9/0.6% for for-profit and 1/0.7% for urban facilities and increased 3.4/2.8% for non-profit and 5.9/4.1% for rural facilities.
CONCLUSIONS: Comorbidity data source may affect performance evaluation. The impact is larger for smaller groups.

[37] Am J Kidney Dis. 2017 Mar;69(3):367-379. doi: 10.1053/j.ajkd.2016.08.030. Epub 2016 Nov 17. Interdialytic Weight Gain: Trends, Predictors, and Associated Outcomes in the International Dialysis Outcomes and Practice Patterns Study (DOPPS).
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.

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.

[38] Am J Kidney Dis. 2017 Jul;70(1):21-29. doi: 10.1053/j.ajkd.2016.10.024. Epub 2017 Jan 19. Serum Potassium and Short-term Clinical Outcomes Among Hemodialysis Patients: Impact of the Long Interdialytic Interval. Brunelli SM, Du Mond C, Oestreicher N, Rakov V, Spiegel DM. Comment in Am J Kidney Dis. 2017 Jul;70(1):4-7.

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.

[39] 18. Clin J Am Soc Nephrol. 2019 Feb 7;14(2):250-260. doi: 10.2215/CJN.08580718. Epub 2019 Jan 31. Fruit and Vegetable Intake and Mortality in Adults undergoing Maintenance Hemodialysis. Saglimbene VM, Wong G, Ruospo M, Palmer SC, Garcia-Larsen V, Natale P, Teixeira-Pinto A, Campbell KL, Carrero JJ, Stenvinkel P, Gargano L, Murgo AM, Johnson DW, Tonelli M, Gelfman R, Celia E, Ecder T, Bernat AG, Del Castillo D, Timofte D, Török M, Bednarek-Skublewska A, Duława J, Stroumza P, Hoischen S, Hansis M, Fabricius E, Felaco P, Wollheim C, Hegbrant J, Craig JC, Strippoli GFM.

BACKGROUND AND OBJECTIVES: Higher fruit and vegetable intake is associated with lower cardiovascular and all-cause mortality in the general population. It is unclear whether this association occurs in patients on hemodialysis, in whom high fruit and vegetable intake is generally discouraged because of a potential risk of hyperkalemia. We aimed to evaluate the association between fruit and
vegetable intake and mortality in hemodialysis.
DESIGN, SETTING, PARTICIPANTS, & MEASUREMENTS: Fruit and vegetable intake was ascertained by the Global Allergy and Asthma European Network food frequency questionnaire within the Dietary Intake, Death and Hospitalization in Adults with ESKD Treated with Hemodialysis study, a multinational cohort study of 9757 adults on hemodialysis, of whom 8078 (83%) had analyzable dietary data. Adjusted Cox regression analyses clustered by country were conducted to evaluate the association between tertiles of fruit and vegetable intake with all-cause, cardiovascular, and noncardiovascular mortality. Estimates were calculated as hazard ratios with 95% confidence intervals (95% CIs).
RESULTS: During a median follow up of 2.7 years (18,586 person-years), there were 2082 deaths (954 cardiovascular). The median (interquartile range) number of servings of fruit and vegetables was 8 (4-14) per week; only 4% of the study population consumed at least four servings per day as recommended in the general population. Compared with the lowest tertile of servings per week (0-5.5, median 2), the adjusted hazard ratios for the middle (5.6-10, median 8) and highest (>10, median 17) tertiles were 0.90 (95% CI, 0.81 to 1.00) and 0.80 (95% CI, 0.71 to 0.91) for all-cause mortality, 0.88 (95% CI, 0.76 to 1.02) and 0.77 (95% CI, 0.66 to 0.91) for noncardiovascular mortality and 0.95 (95% CI, 0.81 to 1.11) and 0.84 (95% CI, 0.70 to 1.00) for cardiovascular mortality, respectively.
CONCLUSIONS: Fruit and vegetable intake in the hemodialysis population is low and a higher consumption is associated with lower all-cause and noncardiovascular death.

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

Source of Systematic Review: • **Title** • **Author** • **Date** • **Citation, including page number** • **URL**	
Quote the guideline or recommendation verbatim about the process, structure or intermediate outcome being measured. If not a guideline, summarize the conclusions from the SR.	
Grade assigned to the **evidence** associated with the recommendation with the definition of the grade	
Provide all other grades and definitions from the evidence grading system	
Grade assigned to the **recommendation** with definition of the grade	
Provide all other grades and definitions from the recommendation grading system	
Body of evidence: • Quantity – how many studies? • Quality – what type of studies?	
Estimates of benefit and consistency across studies	

What harms were identified?	
Identify any new studies conducted since the SR. Do the new studies change the conclusions from the SR?	

_____

1a.4 OTHER SOURCE OF EVIDENCE

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

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

N/A

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

N/A

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

N/A

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

Measure Number (*if previously endorsed*)**:** 0369
Measure Title: Standardized Mortality Ratio for Dialysis Facilities
Date of Submission: 1/5/2020
Type of Measure:

☐ Composite – ***STOP – use composite testing form***	☒ Outcome (*including PRO-PM*)
☐ Cost/resource	☐ Process
☐ 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 5,004, 5,155, 5,279, and 5,409 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	461,495	64
2016	7,316	474,838	64
2017	7,590	486,818	64
2018	7,890	492,837	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

For each year of the four years from 2010-2013, there were 373,002, 382,145, 390,893, and 397,804 patients, respectively.

2019 Submission

For each of the four years from 2015-2018 there were 461,495, 474,838, 486,818 and 492,837 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

Patient Demographics	Percent
Sex (% female)	43.7
ESRD due to Diabetes (%)	48.0
Medicare coverage(%)	
Medicare primary + Medicaid	31.2
Medicare primary + no Medicaid	38.9
HMO	20.9
Medicare secondary/Other	9.1
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	59.9
Black	31.8
Asian/Pacific Islander	5.1
Native American/Alaskan Native	1.1
Other/Unknown	2.1
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.

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
To assess reliability, we assessed the degree to which the SMR was 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 SMR values was assessed across the years 2006, 2007, 2008 and 2009 based on the 5,280 dialysis centers for which an SMR is reported in the 2010 DFRs.

2016 Submission
The reliability of the Standardized Mortality Ratio (SMR) was assessed using data among 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 SMR, 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.

Suppose that there are N facilities with at least 3 expected deaths in the year. Let $T_1,\ldots,T_N$ be the SMR for these facilities. Within each facility, select at random and with replacement $B = 100$ bootstrap samples. 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 SMR_i and repeat the process 100 times. Thus, for the ith facility, we have bootstrapped SMRs of $T^*_{i1},\ldots,T^*_{i100}$. Let S_i^* be the sample variance of this bootstrap sample. From this it can be seen that

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

is a bootstrap estimate of the within-facility variance in the SMR, 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

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

where

$$\bar{T} = \Sigma\, n_i\, T_i \,/\, \Sigma\, n_i$$

is the weighted mean of the observed SMR and

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

is approximately the average facility size (number of patients per facility). 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

$$\text{IUR} = \sigma_b^2 / (\sigma_b^2 + \sigma_{t,w}^2$$

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

The SMR calculation only included facilities with at least 3 expected deaths for each year.

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 SMR 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 SMR across adjacent years (2006 vs. 2007, 2007 vs 2008, and 2008 vs. 2009) ranged from 0.26 to 0.33, indicating that centers with large or small SMR tended to have larger or smaller SMR on the following year. These correlations were highly significant. Similarly, there was persistence in SMRs that were significant from year to year.

For example, there were 4.6% of facilities that had an SMR significantly greater than 1.0 in 2006 (18.3% did not have an SMR). Among those facilities, 30% were again significantly larger than 1.0 in 2007. Of the 3.1% of facilities that were significantly less than 1.0 in 2006, 18% were found to be significantly less than 1.0 in 2007. Among the 74% of facilities that had an SMR not significantly different from 1.0 in 2006, 87% remained in that category 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

Table 1: IUR for One-year SMR 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 Facilities	0.32	5004	0.26	5155	0.30	5279	0.28	5409
Small (<=45)	0.07	1137	0.06	1205	0.03	1241	0.10	1256
Medium (46–85)	0.19	1924	0.16	1967	0.17	2018	0.17	2132
Large (>=86)	0.48	1943	0.39	1983	0.47	2020	0.42	2022

Table 2: IUR for Four-year SMR Overall and by Facility Size, 2010-2013

Facility Size (Number of patients)	IUR	N
All Facilities	0.59	5935
Small (<=135)	0.30	1242
Medium (136–305)	0.45	2320
Large (>=306)	0.73	2373

2019 Submission

The overall IUR for the four-year SMR (2015-2018) is 0.5. The PIUR is 0.77. 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

Overall, we found that IURs for the one-year SMR have a range of 0.26-0.32 across the years 2010, 2011, 2012, and 2013, which indicates that about thirty percent of the variation in the one-year SMR can be attributed to the between-facility differences and about seventy percent to within-facility variation. This value of IUR indicates a relatively **low degree of reliability**. When stratified by facility size, we find that, as expected, larger facilities have greater IUR.

Reliability improved when four-year data were used. Overall, we found that IUR for the four-year SMR for 2010-2013 is 0.59 which indicates that about sixty percent of the variation in the four-year SMR can

be attributed to the between-facility differences (signal) and about forty percent to within-facility variation (noise). This value of IUR indicates a **moderate 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 SMR is effective at detecting outlier facilities and statistically meaningful differences in performance scores across dialysis facilities.

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

Adjusted mortality and fractions of patients achieving K/DOQI guidelines for urea reduction ratios (URRs; > or =65%) and hematocrit levels (> or =33%) were computed for 2,858 dialysis facilities from 1999 to 2002 using national data for patients with end-stage renal disease. Linear and Poisson regression were used to study the relationship between K/DOQI compliance and mortality and between changes in compliance and changes in mortality.

Measure validity is also demonstrated by the relationship of the Standardized Mortality Ratio to other quality of care indicators, including hemoglobin greater than 10 g/dL, urea reduction ratio >= 65%, percent of patients dialyzing with a fistula, and percent of patients dialyzing with a catheter.

2016 Submission

Measure validity is demonstrated by the relationship of the Standardized Mortality Ratio to other quality of care indicators, including the Standardized Hospitalization Ratio (SHR) – Admissions, the Standardized Readmission Ratio (SRR), the Standardized Transfusion Ratio (STrR), percent of patients dialyzing with a fistula, percent of patients dialyzing with a catheter, and percent of patients with Kt/V >=1.2. Spearman's rho is reported for all variables. Because the correlations were approximately the same for the four years 2010-2013, we are reporting only the 2013 correlations.

The measure is also maintained on face validity. It was reviewed by a TEP in 2006 for potential implementation on DFC. The general consensus was the SMR captured meaningful information on

survival that DFC users could use to assess facility quality. 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.

2019 Submission

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

Negative Relationships

- Vascular Access: Standardized Fistula Rate (SFR) – We expect a negative association between SFR and SMR. 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 mortality. Higher rates of the facility level SFR will be negatively associated with mortality as measured by SMR.
- Kt/V ≥ 1.2: We expect a negative association between the facility percentage of patients with Kt/V>= 1.2 and SMR. 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 adverse outcomes. 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 mortality. Higher rates of the facility level percentage of patients with adequate dialysis (facility percentage Kt/V≥ 1.2) will be negatively associated with SMR.

Positive Relationships

- Vascular Access: Long-term catheter rate (catheter in use >=3 continuous months) – We expect a positive association between the long-term catheter rate and SMR. 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 be at higher risk of mortality. Higher long-term catheter rates will be positively associated with SMR.
- SHR: We expect a positive association between SHR and SMR. Patients who require acute medical care in the hospital 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.
- SRR: We expect a positive association between SRR and SMR. Both hospitalization and readmission are a reflection of hospital utilization and increased comorbidity burden. Additionally, patients readmitted after a recent discharge indicates they still require acute medical attention or experience other post-discharge complications placing them at higher risk for mortality.

- STrR: We expect a positive association between STrR and SMR. Patients with severe anemia may require hospitalization and blood transfusion, placing them at risk for other adverse events and potentially higher risk for mortality.

The measure is also maintained on face validity. It was reviewed by a TEP in 2006 for potential implementation on DFC. The general consensus was the SMR captured meaningful information on survival that DFC users could use to assess facility quality. 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.

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

2011 Submission

In 2002, facilities in the lowest quintile of K/DOQI compliance for urea reduction ratio (URR) and hematocrit guidelines had 22% and 14% greater mortality rates ($P < 0.0001$) than facilities in the highest quintile, respectively. A 10-percentage point increase in fraction of patients with a URR of 65% or greater was associated with a 2.2% decrease in mortality ($P = 0.0006$), and a 10-percentage point increase in percentage of patients with a hematocrit of 33% or greater was associated with a 1.5% decrease in mortality ($P = 0.003$). Facilities in the highest tertiles of improvement for URR and hematocrit had a change in mortality rates that was 15% better than those observed for facilities in the lowest tertiles ($P < 0.0001$).

Please see the following publication for further details: Wolfe RA, Hulbert-Shearon TE, Ashby VB, Mahadevan S, Port FK. Improvements in dialysis patient mortality are associated with improvements in urea reduction ratio and hematocrit, 1999 to 2002. Am J Kidney Dis. 2005 Jan;45(1):127-35.

2016 Submission

SHR-Admissions: rho=0.20, p<.0001

SRR-Readmissions: rho=0.10, p<.0001

STrR: rho=0.21, p<.0001

AV Fistula: rho= -0.11, p<.0001

Catheter: rho=0.13, p<.0001

Hemodialysis patients with Kt/V>=1.2: rho= -0.04, p<.0001

2019 Submission

Table 3. Correlation between SMR and other Measures, 2018

Measure	Spearman's rho	p-value
SFR	-0.08	<0.0001
Kt/V >=1.2	-0.16	<0.0001
Long-term Catheter	0.07	<0.0001
SHR	0.15	<0.0001
SRR	0.08	<0.0001
STrR	0.16	<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

As expected, the SMR is positively correlated with the SHR-Admissions (rho=0.20, p<.0001), SRR-Readmissions (rho=0.10, p<.0001), and the STrR (rho=0.21, p<.0001); higher standardized mortality rates in facilities are associated with higher standardized hospitalization rates, higher standardized readmissions rates and higher standardized transfusion rates. The SMR is negatively correlated with percent of patients in the facility with AV Fistula (rho= -0.11, p<.0001); lower standardized mortality rates are associated with higher rates of AV Fistula use. On the other hand, the SMR is positively correlated with catheter use (rho=0.13, p<.0001), indicating that higher values of SMR are associated with increased use of catheters. The SMR is also found to be negatively correlated (rho= -0.04, p<.0001) with the percent of hemodialysis patients with Kt/V>=1.2, again in the direction expected. Lower SMRs are associated with a higher percentage of patients receiving adequate dialysis dose.

2019 Submission

SMR is correlated with each of the quality performance measures in the expected direction. All correlations are statistically significant. As expected, the SMR is positively correlated for each individual year with the SHR-Admissions, SRR-Readmissions, and the STrR. The SMR is negatively correlated with the percent of hemodialysis patients with Kt/V>=1.2, in the direction expected indicting lower SMRs are associated with a higher percentage of patients receiving adequate dialysis dose. The SMR is negatively correlated with the percentage of patients in the facility with an AV Fistula as measured by SFR indicating lower standardized mortality rates are associated with a higher standardized fistula rate. On the other hand, the SMR is positively correlated with long-term catheter rates indicating that higher values of SMR are associated with higher rates of long-term catheters.

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*)

N/A

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*)

N/A

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*)

N/A

_____

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 146 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.
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The methods for development of the risk factor models have been published and documented previously (Wolfe 1992; Wolfe 2001). The final risk adjustment is based on a Cox or relative risk model. In this model, covariates are taken to act multiplicatively on the death 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) and Kalbfleisch and Prentice (2002). All analyses are performed using SAS.

In the SMR, adjustment is made for patient age, sex, race, ethnicity, cause of ESRD, duration of ESRD, nursing home status, BMI at incidence, comorbidities at incidence, prevalent comorbidities, and calendar year. The SMR is also adjusted for state population death rates.

Below we discuss factors considered for inclusion in the statistical risk model, with emphasis on new factors considered since the last cycle of NQF maintenance endorsement in 2011. We present results and discussion supporting the selection of specific risk factors in the model.

Risk adjustment factors were selected for testing based on several considerations, specifically clinical criteria, expert input, factors identified in the literature as associated with mortality, and data availability. We began with a large set of patient characteristics, comorbidities (at ESRD incidence and prevalent), anthropometrics, and other characteristics. Facility characteristics were also considered. Risk factors were evaluated for appropriateness of the adjustment. For instance, it is important not to adjust for factors that reflect the results of treatment. Factors considered appropriate and supported in the literature were then investigated with statistical models, including interactions between sets of adjusters, to determine if they were empirically related to mortality. Risk factors were also evaluated for face validity as potential predictors of mortality. Finally, SDS/SES factors were evaluated based on appropriateness (whether related to disparities in care), empirical association with the outcome, and support in published literature.

Consideration of prevalent comorbidities as risk adjusters, in addition to incident comorbidities, is in part a response to stakeholder interest to adjust for more current (prevalent) comorbidities to reflect the current health status of dialysis patients, and conditions associated with mortality. 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. 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.

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 comorbidity diagnoses (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

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 in the model results section.

Consideration of SES/SDS risk factors:

In addition to clinical factors, we evaluated patient and area-level SDS/SES factors as risk adjusters. These were in addition to the current SDS factors of race, ethnicity, and sex. Race and sex were included in the original SMR calculation and ethnicity was added to the model in 2005.

The relationships among individual SDS factors, socioeconomic disadvantage and mortality is well-established in the general population (Singh and Siahpush, 2006; Williams, 2006; Williams and Collins, 2001). Further, individual and market or area-level measures of deprivation have been shown to contribute independently to higher mortality (Smith et al., 1998).

Area-level income and residential segregation specifically have been shown to be associated with poorer outcomes, but particularly so for racial minorities, suggesting the interplay of patient-level (race) and area-level factors related to lower income, neighborhood poverty, segregation, levels of educational attainment, and unemployment levels that jointly influence key health outcomes in mortality and morbidity (Williams, 2006; Williams and Collins, 2001). For example, Williams (2006) explains that differences in health outcomes and mortality by race persist, even after accounting for levels of SES. This suggests the potential added effect of historical and institutional discrimination (e.g., segregation; restricted educational access; fewer health-related resources in poor neighborhoods; no insurance or Medicaid status) that have cumulatively over time led to reduced access to care. Residential segregation of blacks in the U.S., Williams and Collins argue, is a primary cause of SES differences that in turn have resulted in a high prevalence of chronic diseases and related differences in health care outcomes such as mortality (Williams and C Collins 2001, p 404-406).

The relationship between race and mortality, as well as both race and area-level SES factors and mortality in the dialysis population, is also well documented (e.g., Burrows et al, 2014; Crews et al , 2001; Eisenstein et al, 2009; Johns et al , 2014; Kucirka et al, 2010; Ricks et al, 2011; Kalbfleisch et al., 2015; Rodriguez et al, 2007; Kimmel et al, 2013; Streja et al, 2011; Yan et al., 2013; Yan et al, 2013). However, the direction of the relationship between race and mortality is inverted relative to the general population, with lower observed mortality in blacks on chronic dialysis compared to whites, although the relationship is mediated by sociodemographic and clinical factors (Norris et al., 2008; Powe, 2006; Cowie et al. 1994). For example, while black ESRD patients overall have been observed to have lower mortality compared to whites, some studies have shown this difference is attenuated or disappears once accounting for one or more area level SES factors (Eisenstein et al 2009; Johns et al 2014; Rodriguez et al 2007; Crews et al., 2011; Ricks et al., 2011; Streja et al 2011; Johns et al 2014; Yan 2013; Yan et al 2014).

Differences based on clinical factors and Hispanic ethnicity have also been observed to impact lower mortality (Streja et al 2011; Johns et al 2014; Yan 2013; Yan et al 2013; Ricks et al 2011). Taken together

race and ethnicity are shown to be strongly associated with mortality but in different clinical pathways after accounting for specific clinical markers of health status. Race was included as an adjuster in the prior version of SMR because accounting for within-facility racial differences helps to clarify disparities in quality of healthcare provided to patients with ESRD (Kalbfleisch et al., 2015).

Females in the general population have lower mortality rates (CDC National Vital Statistics Reports, 2012) than males. Adjustment for sex allows for a fair comparison between dialysis facilities with patient populations that have a different mix of males and females.

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 mortality. For example, Curtin et al (AJKD 1996) found that measures of functional status were higher in patients that were employed.

Insurance status is also related to health outcomes but this has not been studied extensively within the dialysis population as it relates to mortality. However some evidence suggests a link between dual eligibles and hospital utilization (Wright et al., 2015).

In sum these studies suggest notable associations with mortality differences when taking into account patient level SDS factors (race, sex, ethnicity), and area level SES factors. Additionally, employment status and type of insurance coverage (specifically Medicare-Medicaid dual eligibility) suggest a proximate relationship to health outcomes that may have downstream impacts on mortality.

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 on 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).

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The methods for development of the risk factor models have been published and documented previously (Wolfe 1992; Wolfe 2001). The final risk adjustment is based on a Cox or relative risk model. In this model, covariates are taken to act multiplicatively on the death 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) and Kalbfleisch and Prentice (2002). All analyses are performed using SAS.

The denominator of SMR for a facility is the expected number of deaths from the patient-records meeting the inclusion criteria, based on the number of days attributed to that facility (the assignment rule will be detailed later), if the facility conforms to the national norm. Specifically, the expectation is calculated using a two-stage model. At Stage 1, we fit a Cox model (Cox, 1972) stratified by facility and adjusted for patient age, race, ethnicity, sex, diabetes, duration of ESRD, nursing home status, patient comorbidities, calendar year, and body mass index (BMI) at incidence. This stratified model allows each facility to have a distinct baseline survival function while retaining the same regression coefficients of all the adjusters across all the facilities. Stratification by facility avoids estimating facility effects directly and also reduces computational burden. A linear predictor using the estimates of regression coefficients will be computed for each patient and will be used as the offset term in the Stage 2 modeling. At Stage 2, we fit an unstratified Cox model, which includes the offset term from Stage 1 model as well as the race-specific age-adjusted state population death rates. The baseline hazard or survival function of this model has national norm interpretations. With the fitted model at Stage 2, we compute the expected

probability of death for each patient based on the aforementioned adjusters and the number of days assigned to a facility. The denominator of SMR for a facility is then the summation of expected probabilities of death from all the patients assigned to that facility.

The patient characteristics included in the stage 1 model as covariates are:

- Age: Age is included as a piecewise continuous variable with different coefficients based on whether the patient is 0-13 years old, 14-60 years old, or 61+ years old.
- Sex
- Race: White, Black, Asian/PI, Native American or other
- Ethnicity: Hispanic, non-Hispanic or unknown
- Diabetes as cause of ESRD
- Duration of ESRD:
    - Less than one year
    - 1-2 years
    - 2-3 years
    - 3+ years
- 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 other than as primary 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 Medicare covered months in prior calendar year
- Calendar year

Beside main effects, two-way interaction terms between age, race, ethnicity, sex, duration of ESRD and diabetes as cause of ESRD are also included:

- Age and Race: Black
- Ethnicity and Race: Non-White
- Diabetes as cause of ESRD and Race
- Diabetes as cause of ESRD and Duration of ESRD
- Duration of ESRD: less than or equal to 1 year and Race
- Sex and Race: Black

Below we discuss how factors were considered for inclusion in the statistical risk model.

Risk adjustment factors were selected for testing based on several considerations, specifically clinical criteria, expert input, factors identified in the literature as associated with mortality, and data availability. We began with a large set of patient demographics, comorbidities (at ESRD incidence and prevalent), anthropometrics, and other characteristics. Facility characteristics were also considered. Risk factors were evaluated for appropriateness of the adjustment. For instance, it is important not to adjust for factors that reflect the results of treatment. Factors considered appropriate and supported in the literature were then investigated with statistical models, including interactions between sets of adjusters, to determine if they were empirically related to mortality. Risk factors were also evaluated for face validity as potential predictors of mortality.

Consideration of prevalent comorbidities as risk adjusters, in addition to incident comorbidities, is in part a response to stakeholder interest to adjust for more current (prevalent) comorbidities to reflect the current health status of dialysis patients, and conditions associated with mortality. CMS contracted with UM-KECC to convene a 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-measures. Specific 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 individual ICD-9 diagnosis codes 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 SMR 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 SMR 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. A patient is considered to have a particular prevalent comorbid condition if one of the ICD-10

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.

For this submission we also considered inclusion of an indicator for Medicare Advantage time at risk during the previous calendar year, as in the SHR measure. However, this variable was not statistically significant for SMR and the coefficient was very small therefore it was not included in the final SMR model.

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 support in published literature (see section 2b3.3b).

2b3.2. If an outcome or resource use component measure is <u>not risk adjusted or stratified</u>, provide <u>rationale and analyses</u> 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 <u>and</u> 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?

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)**

In addition to clinical factors, we evaluated patient and area-level SDS/SES social risk factors as risk adjusters. These were in addition to the current inclusion of race, ethnicity, and sex included in the currently endorsed and implemented SMR as described in the 2016 submission.

The relationships among individual SDS factors, socioeconomic disadvantage and mortality is well-established in the general population (Singh and Siahpush, 2006; Williams, 2006; Williams and Collins,

2001). Further, individual and market or area-level measures of deprivation have been shown to contribute independently to higher mortality (Smith et al., 1998).

The relationship between race and mortality, Hispanic ethnicity and mortality, as well as both race and area-level SES factors and mortality in the dialysis population, is also well documented (e.g., Burrows et al, 2014; Crews et al , 2001; Eisenstein et al, 2009; Johns et al , 2014; Kucirka et al, 2010; Ricks et al, 2011; Kalbfleisch et al., 2015; Rodriguez et al, 2007; Kimmel et al, 2013; Streja et al, 2011; Yan et al., 2013; Yan et al, 2013). However, the direction of the relationship between race and mortality is inverted relative to the general population, with lower observed mortality in blacks on chronic dialysis compared to whites, although the relationship is mediated by sociodemographic and clinical factors (Norris et al., 2008; Powe, 2006; Cowie et al. 1994).

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.

References:

Burrows N, Cho P, Bullard KM, Narva A, and Eggers P. Survival on Dialysis Among American Indians and Alaska Natives With Diabetes in the United States, 1995–2010. American Journal of Public Health. Supplement 3, 2014, Vol 104, No. S3. S490.

CDC National Vital Statistics Reports, Vol. 61, No. 6, October 10, 2012, Table A

Cowie C, Port F, Rust K, Harris M: Differences In Survival Between Black And White Patients With Diabetic End-Stage Renal Disease. Diabetes Care 17: 681–687, 1994

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

Crews D, Sozio S, Liu Y, Coresh J, and Powe N. Inflammation and the Paradox of Racial Differences in Dialysis Survival. J Am Soc Nephrol 22: 2279–2286, 2011.

Curtin R, Oberley E, Sacksteder P, and Friedman A. Differences Between Employed and Nonemployed Dialysis Patients. AJKD Vol 27:4. (April) 1996. 533-540.

Eisenstein E, Sun J, Anstrom K, Stafford J, Szczech L, Muhlbaier L, Mark D. Do Income Level and Race Influence Survival in Patients Receiving Hemodialysis? The American Journal of Medicine (2009) 122, 170-180.

Johns T, Estrella M, Crews D, Appel L, Anderson C, Ephraim P, Cook C, and Boulware L. Neighborhood Socioeconomic Status, Race, and Mortality in Young Adult Dialysis Patients. Am Soc Nephrol 25: epub, 2014.

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

Kalbfleisch J, Wolfe R, Bell S, Sun R, Messana J, Shearon T, Ashby V, Padilla R, Zhang M, Turenne M, Pearson J, Dahlerus C, and Li Y. Risk Adjustment and the Assessment of Disparities in Dialysis Mortality Outcomes. J Am Soc Nephrol 26: 2641–2645, 2015

Kimmel P, Fwu CW, and Eggers P. Segregation, Income Disparities, and Survival in Hemodialysis Patients. JASN. February 2013 vol. 24 no. 2 293-301.

Kucirka L, Grams M, Lessler J, Hall E, James J, Massie A, Montgomery R, and Segev D. Age and Racial Disparities in Dialysis Survival. JAMA. 2011 August 10; 306(6): 620–626. doi:10.1001/jama.2011.1127

Norris K, Mehrotra R, Nissenson A. Racial Differences in Mortality and ESRD. American Journal of Kidney Diseases, Volume 52, Issue 2, August 2008, Pages 205–208.

Powe, NR. Reverse Race And Ethnic Disparities In Survival Increase With Severity Of Chronic Kidney Disease: What Does This Mean? Clin J Am Soc Nephrol 1: 905–906, 2006;

Ricks R, Molnar M, Kovesdy C, Kopple J, Norris K, Mehrotra R, Nissenson A, Arah O, Greenland S, and Kalantar-Zadeh K. Racial and Ethnic Differences in the Association of Body Mass Index and Survival in Maintenance Hemodialysis Patients. Am J Kidney Dis. 2011 October ; 58(4): 574–582.

Rodriguez R, Sen S, Mehta K, Moody-Ayers S, Bacchetti P, and O'Hare A. Geography Matters: Relationships among Urban Residential Segregation, Dialysis Facilities, and Patient Outcomes. Ann Intern Med. 2007;146:493-501.

Singh, G. Area Deprivation and Widening Inequalities In US Mortality, 1969–1998. Am J Public Health. 2003;93(7):1137–1143

University of Wisconsin School of Medicine Public Health. 2015 Area Deprivation Index v2.0. Downloaded from https://www.neighborhoodatlas.medicine.wisc.edu. Accessed 10/31/2018.

Singh G and Siahpush M. Widening Socioeconomic Inequalities In US Life Expectancy, 1980–2000. Int. J. Epidemiol. (August 2006) 35 (4): 969-979

Smith G, Hart C, Watt G, Hole D, Hawthorne V. Individual Social Class, Area-Based Deprivation, Cardiovascular Disease Risk Factors, And Mortality: the Renfrew and Paisley Study. J Epidemiol Community Health 1998; 52:399-405

Streja E, Kovesdy C, Molnar M, Norris K, Greenland S, Nissenson A, Kopple J, and Kalantar-Zadeh K. Role of Nutritional Status and Inflammation in Higher Survival of African American and Hispanic Hemodialysis Patients. Am J Kidney Dis. 2011 June ; 57(6): 883–893.

University of Wisconsin School of Medicine Public Health. 2013 Area Deprivation Index v1.5. Downloaded from https://www.neighborhoodatlas.medicine.wisc.edu/ October 31, 2018.

Williams D. "Race, Socioeconomic Status, and Health: The Added Effects of Racism and Discrimination. Annals of the New York Academy of Sciences. Volume 896, Issue 1, Article first published online: 6 February 2006.

Williams D, and Collins C, Racial Residential Segregation: A Fundamental Cause of Racial Disparities in Health. Public Health Reports / September–October 2001. Volume 116. 404-416.

Wolfe RA et al: New Dialysis Facility Mortality Statistics (Smrs) Adjust For More Patient Characteristics. J Am Soc Nephrol 2001; 12; A1802

Wolfe R et al. Using USRDS Generated Mortality Tables To Compare Local ESRD Mortality Rates To National Rates. Kidney Int 1992; 42: 991-96

Wright B, Potter A, and Trivedi A. Federally Qualified Health Center Use Among Dual Eligibles: Rates Of Hospitalizations And Emergency Department Visits Health Affairs, 34, no.7 (2015):1147-1155

Yan G, Norris K, Xin W, Ma J, Yu A, Greene T, Yu W, and Cheung A. Facility Size, Race and Ethnicity, and Mortality for In-Center Hemodialysis. J Am Soc Nephrol 24: 2062–2070, 2013. doi: 10.1681.

Yan G, Norris K, Yu A, Ma J, Greene T, Yu W, and Cheung A. The Relationship of Age, Race, and Ethnicity with Survival in Dialysis Patients. Clin J Am Soc Nephrol 8: 953–961, 2013. doi: 10.2215.

2b3.4a. What were the statistical results of the analyses used to select risk factors?
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Analyses of Comorbidities and other Clinical Factors

Table 3a presents the SMR model coefficients. Of note, it shows the coefficients on the prevalent comorbidities that were recommended by the TEP as additional risk adjusters (i.e., in addition to the risk adjusters in the SMR model since the 2011 endorsement maintenance review).

Table 3a. Model Coefficients, Data Years 2010–2013

Covariate	Coefficient	p-value
Comorbidities at start of ESRD		
At least of the comorbidities listed below	0.15783	<.0001
Atherosclerotic heart disease	0.04559	<.0001
Other cardiac disease	0.06736	<.0001
Diabetes (all types including diabetic retinopathy)*	0.01596	0.0389
Congestive heart failure	0.12221	<.0001
Inability to ambulate	0.14953	<.0001
Chronic obstructive pulmonary disease	0.07399	<.0001
Inability to transfer	0.11727	<.0001
Malignant neoplasm, cancer	0.10791	<.0001
Peripheral vascular disease	0.05252	<.0001
Cerebrovascular disease, CVA, TIA	0.01484	0.0311
Tobacco use (current smoker)	0.10783	<.0001
Alcohol dependence	0.03135	0.0989
Drug dependence	0.07436	0.0008
No Medical Evidence (CMS-2728) Form	0.0115	0.7696
Cause of ESRD		
Diabetes	0.14834	<.0001
Missing	-0.02574	0.2855
Sex: Female	-0.07704	<.0001
Age		
Age (continuous)	-0.05786	0.0003
Age spline at 14	0.08753	<.0001
Age spline at 60	0.00651	<.0001
Race: black X age interaction		
Age (continuous)	-0.0371	0.1983
Age spline at 14	0.03412	0.2384
Age spline at 60	0.0009396	0.4437
Patient in nursing home	0.31026	<.0001
Incident BMI		
Log of BMI (continuous)	-0.48904	<.0001
Log of BMI spline at 35	0.57016	<.0001
BMI Missing	0.14771	<.0001
Race		
White	Reference	-
Black	0.31856	0.4275
Asian/PI	-0.33283	<.0001
Native American	-0.12939	0.0015
Other	-0.25062	<.0001
Time on ESRD		
< 1 year	-0.18009	<.0001
1 to 2 years	-0.21764	<.0001
2 to 3 years	-0.17079	<.0001
3+ years	Reference	-
Calendar year		
2010	0.1289	<.0001
2011	0.10334	<.0001
2012	0.00509	0.3735
2013	Reference	-
Ethnicity		
Hispanic	-0.31125	<.0001
Non-Hispanic ethnicity	Reference	
Unknown ethnicity	0.09259	0.0082

Covariate	Coefficient	p-value
Ethnicity X race: nonwhite interaction		
Hispanic ethnicity	0.30208	<.0001
Unknown ethnicity	0.12773	0.0004
Race X diabetes as cause of ESRD interaction		
Asian/PI	0.04491	0.0405
Black	-0.08505	<.0001
Native American	-0.00639	0.8865
Other	0.10269	0.0266
Time with ESRD X diabetes as cause of ESRD interaction		
< 1 year	-0.20115	<.0001
1 to 2 years	-0.11321	<.0001
2 to 3 years	-0.04516	0.0004
3+ years	Reference	-
Time on ESRD: < 1 year X race interaction		
Asian/PI	-0.13672	<.0001
Black	0.03974	0.0003
Native American	-0.10883	0.0344
Other	0.26902	<.0001
Time on ESRD: < 1 year X sex: female interaction	0.00915	0.3193
Sex: female X cause of ESRD: diabetes interaction	-0.00839	0.3009
Race: black X sex: female interaction	0.06686	<.0001

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

Table 3b. Prevalent Comorbidity Coefficients, Data Years 2010–2013

ICD-9 Description	ICD-9 Code	Coefficient	P-value
Sarcoidosis	135	0.0498	0.1881
Malign neopl prostate	185	-0.06496	<.0001
Malign neopl thyroid	193	-0.24613	<.0001
Oth severe malnutrition	262	0.17484	<.0001
Chr airway obstruct NEC	496	0.16266	<.0001
Postinflam pulm fibrosis	515	0.15118	<.0001
Malignant neopl rectum	1541	0.30273	<.0001
Mal neo liver, primary	1550	0.36764	<.0001
Mal neo upper lobe lung	1623	0.27901	<.0001
Mal neo bronch/lung NOS	1629	0.41213	<.0001
Malig neo bladder NOS	1889	0.19631	<.0001
Malig neopl kidney	1890	-0.04592	0.0198
Secondary malig neo lung	1970	0.5234	<.0001
Second malig neo liver	1977	0.90921	<.0001
Secondary malig neo bone	1985	0.71735	<.0001
Malignant neoplasm NOS	1991	0.35314	<.0001

ICD-9 Description	ICD-9 Code	Coefficient	P-value
Protein-cal malnutr NOS	2639	0.19068	<.0001
Dis urea cycle metabol	2706	-0.01549	0.7273
Senile dementia uncomp	2900	0.07334	<.0001
Drug withdrawal	2920	0.13901	0.0014
Mental disor NEC oth dis	2948	0.16473	<.0001
Cereb degeneration NOS	3319	0.10725	<.0001
Aut neuropthy in oth dis	3371	0.02175	0.1983
Grand mal status	3453	-0.00454	0.8984
Anoxic brain damage	3481	0.2873	<.0001
Cerebral edema	3485	0.21974	<.0001
Idio periph neurpthy NOS	3569	0.03128	0.0003
Neuropathy in diabetes	3572	0.0258	0.0042
Intermed coronary synd	4111	0.05768	<.0001
Angina pectoris NEC/NOS	4139	0.00621	0.5314
Prim pulm hypertension	4160	0.05884	0.0002
Chr pulmon heart dis NEC	4168	0.1898	<.0001
Prim cardiomyopathy NEC	4254	0.23084	<.0001
Cardiomyopath in oth dis	4258	0.04292	0.0329
Atriovent block complete	4260	0.15129	<.0001
Parox ventric tachycard	4271	0.18283	<.0001
Parox tachycardia NOS	4272	0.07202	0.0747
Subdural hemorrhage	4321	0.13039	<.0001
Aortic atherosclerosis	4400	0.03595	0.0233
Lower extremity aneurysm	4423	0.02375	0.4642
Periph vascular dis NOS	4439	0.16444	<.0001
Stricture of artery	4471	-0.02833	0.0635
Oth inf vena cava thromb	4532	0.30687	<.0001
Emphysema NEC	4928	0.07809	<.0001
Bronchiectas w/o ac exac	4940	0.03515	0.3221
Food/vomit pneumonitis	5070	0.1607	<.0001
Lung involv in oth dis	5178	0.15956	0.0088
Regional enteritis NOS	5559	0.12126	0.0002
Ulceratve colitis unspcf	5569	0.02044	0.5561
Chr vasc insuff intest	5571	0.13302	<.0001
Paralytic ileus	5601	-0.01047	0.5007
Intestinal obstruct NOS	5609	0.08494	<.0001
Alcohol cirrhosis liver	5712	0.15572	<.0001
Cirrhosis of liver NOS	5715	0.41697	<.0001
Hepatic encephalopathy	5722	0.31225	<.0001
Portal hypertension	5723	0.22903	<.0001

ICD-9 Description	ICD-9 Code	Coefficient	P-value
Oth sequela, chr liv dis	5728	0.2376	<.0001
Chronic pancreatitis	5771	0.17966	<.0001
Chronic skin ulcer NEC	7078	0.14188	<.0001
Syst lupus erythematosus	7100	0.19554	<.0001
Systemic sclerosis	7101	0.39484	<.0001
Rheumatoid arthritis	7140	0.0896	<.0001
Inflamm polyarthrop NOS	7149	-0.02268	0.6699
Sacroiliitis NEC	7202	0.04558	0.2878
Gangrene	7854	0.17237	<.0001
Cachexia	7994	0.33328	<.0001
Fracture of pubis-closed	8082	0.11422	0.0001
Pelvic fracture NOS-clos	8088	0.05103	0.1367
Fx neck of femur NOS-cl	8208	0.04397	0.0051
Amput below knee, unilat	8970	-0.09002	<.0001
Amputat bk, unilat-compl	8971	-0.01234	0.7926
Amput above knee, unilat	8972	-0.11732	<.0001
Amputat leg, unilat NOS	8974	-0.08497	0.064
Candidal esophagitis	11284	0.21728	<.0001
Oth lymp unsp xtrndl org	20280	0.20078	<.0001
Mult mye w/o achv rmson	20300	0.41084	<.0001
Ch lym leuk wo achv rmsn	20410	0.37957	<.0001
Essntial thrombocythemia	23871	0.12789	0.0003
Low grde myelody syn les	23872	0.15381	0.0017
Myelodysplastic synd NOS	23875	0.20555	<.0001
DMII wo cmp nt st uncntr	25000	0.0721	<.0001
DMII wo cmp uncntrld	25002	-0.01161	0.0705
DMII keto nt st uncntrld	25010	0.0982	0.0001
DMII ketoacd uncontrold	25012	0.14458	<.0001
DMI ketoacd uncontrold	25013	0.28449	<.0001
DMII hprosmlr uncontrold	25022	0.04571	0.2251
DMII renl nt st uncntrld	25040	0.03375	<.0001
DMI renl nt st uncntrld	25041	0.07679	<.0001
DMII ophth nt st uncntrl	25050	0.00575	0.482
DMI ophth uncntrld	25053	0.0629	0.0443
DMII neuro nt st uncntrl	25060	-0.00885	0.2742
DMI neuro nt st uncntrld	25061	0.03226	0.0203
DMII neuro uncntrld	25062	-0.004	0.7193
DMI neuro uncntrld	25063	0.05321	0.037
DMII circ nt st uncntrld	25070	-0.01444	0.0857
DMI circ nt st uncntrld	25071	-0.02272	0.1652

ICD-9 Description	ICD-9 Code	Coefficient	P-value
DMII circ uncntrld	25072	0.00435	0.7765
DMII oth nt st uncntrld	25080	0.12132	<.0001
DMI oth nt st uncntrld	25081	0.09973	<.0001
DMII oth uncntrld	25082	0.05006	0.0001
DMI oth uncntrld	25083	0.14618	<.0001
Glucocorticoid deficient	25541	0.31984	<.0001
Amyloidosis NEC	27739	0.32816	<.0001
Metabolism disorder NEC	27789	0.13233	0.0078
Morbid obesity	27801	0.00932	0.3779
Obesity hypovent synd	27803	-0.02953	0.3107
Sickle cell disease NOS	28260	0.61472	<.0001
Antin chemo indcd pancyt	28411	0.39212	<.0001
Other pancytopenia	28419	0.17159	<.0001
Neutropenia NOS	28800	0.19529	<.0001
Drug induced neutropenia	28803	0.29116	<.0001
Prim hypercoagulable st	28981	0.15977	<.0001
Senile delusion	29020	0.1114	0.0105
Vascular dementia,uncomp	29040	0.10829	<.0001
Dementia w/o behav dist	29410	0.10461	<.0001
Dementia w behavior dist	29411	0.12167	<.0001
Demen NOS w/o behv dstrb	29420	0.15134	<.0001
Schizophrenia NOS-unspec	29590	0.16904	<.0001
Depress psychosis-unspec	29620	0.08783	<.0001
Recurr depr psychos-unsp	29630	0.04595	0.0459
Recur depr psych-severe	29633	0.04953	0.0214
Bipolar disorder NOS	29680	0.03951	0.0718
Bipolar disorder NEC	29689	0.0765	0.1406
Episodic mood disord NOS	29690	-0.0061	0.8254
Alcoh dep NEC/NOS-unspec	30390	0.02262	0.4481
Alcoh dep NEC/NOS-remiss	30393	-0.0592	0.1194
Opioid dependence-unspec	30400	0.23963	<.0001
Opioid dependence-contin	30401	0.10216	0.0083
Drug depend NOS-unspec	30490	0.09283	0.0412
Psymotr epil w/o int epi	34540	-0.05696	0.1739
Epilep NOS w/o intr epil	34590	0.10419	<.0001
Critical illness myopthy	35981	-0.10948	0.0009
Prolif diab retinopathy	36202	-0.056	<.0001
Mod nonprolf db retinoph	36205	-0.10539	0.0017
Diabetic macular edema	36207	-0.16216	<.0001
Hyp ht dis NOS w ht fail	40291	-0.01224	0.5579

ICD-9 Description	ICD-9 Code	Coefficient	P-value
Subendo infarct, initial	41071	0.28073	<.0001
AMI NEC, unspecified	41080	-0.00835	0.8738
AMI NOS, unspecified	41090	0.04091	0.0037
Ac ischemic hrt dis NEC	41189	0.07088	0.0013
Pulm embol/infarct NEC	41519	0.02084	0.2221
Atrial fibrillation	42731	0.24876	<.0001
Atrial flutter	42732	0.06245	<.0001
Sinoatrial node dysfunct	42781	-0.04157	<.0001
Crbl emblsm w infrct	43411	0.18777	<.0001
Crbl art ocl NOS w infrc	43491	0.12749	<.0001
Athscl extrm ntv art NOS	44020	0.02718	0.0013
Ath ext ntv at w claudct	44021	0.02956	0.0173
Ath ext ntv at w rst pn	44022	0.0837	<.0001
Ath ext ntv art ulcrtion	44023	0.05416	<.0001
Dsct of thoracic aorta	44101	0.11966	0.0452
Periph vascular dis NEC	44389	0.02878	0.0596
Deep phlebitis-leg NEC	45119	-0.04641	0.1151
Ac DVT/emb prox low ext	45341	0.08701	<.0001
Ch DVT/embl low ext NOS	45350	0.05663	0.1025
Ch DVT/embl prox low ext	45351	0.03822	0.3528
Ch emblsm subclav veins	45375	0.16767	<.0001
Ac DVT/embl up ext	45382	0.07744	0.0026
Ac emblsm axillary veins	45384	0.07944	0.049
Ac embl internl jug vein	45386	0.08068	0.0006
Ac embl thorac vein NEC	45387	0.07384	0.0288
Esoph varice oth dis NOS	45621	0.18859	<.0001
Obs chr bronc w(ac) exac	49121	0.13193	<.0001
Obs chr bronc w ac bronc	49122	-0.0088	0.5824
Chronic obst asthma NOS	49320	0.01834	0.1388
Ch obst asth w (ac) exac	49322	0.01286	0.4885
Ac resp flr fol trma/srg	51851	0.02845	0.355
Ot pul insuf fol trm/srg	51852	-0.06297	0.3178
Other pulmonary insuff	51882	0.09857	<.0001
Chronic respiratory fail	51883	0.11434	<.0001
Acute & chronc resp fail	51884	0.12628	<.0001
Gastrostomy comp - mech	53642	0.15365	<.0001
Fecal impaction	56032	0.04821	0.1281
Pressure ulcer, low back	70703	0.22465	<.0001
Pressure ulcer, hip	70704	0.24053	<.0001
Pressure ulcer, buttock	70705	0.09838	<.0001

ICD-9 Description	ICD-9 Code	Coefficient	P-value
Ulcer of lower limb NOS	70710	0.09412	<.0001
Ulcer other part of foot	70715	0.08756	<.0001
Ulcer oth part low limb	70719	0.16587	<.0001
Pyogen arthritis-unspec	71100	-0.04327	0.3753
Pyogen arthritis-l/leg	71106	0.02859	0.4542
Ac osteomyelitis-unspec	73000	-0.04987	0.131
Ac osteomyelitis-ankle	73007	-0.08917	<.0001
Ac osteomyelitis NEC	73008	-0.03235	0.307
Osteomyelitis NOS-hand	73024	0.24478	<.0001
Osteomyelitis NOS-ankle	73027	-0.12149	<.0001
Path fx vertebrae	73313	0.22531	<.0001
Aseptic necrosis femur	73342	0.10754	0.0188
Asept necrosis bone NEC	73349	0.15539	0.006
Coma	78001	0.21242	<.0001
Convulsions NEC	78039	0.09323	<.0001
Fx femur intrcaps NEC-cl	82009	-0.00952	0.7647
Fx femur NOS-closed	82100	-0.02136	0.4055
React-indwell urin cath	99664	0.05432	0.0555
Compl heart transplant	99683	0.09947	0.1582
Asymp hiv infectn status	V08	0.46221	<.0001
Heart transplant status	V421	0.19932	0.0002
Liver transplant status	V427	0.03733	0.2656
Trnspl status-pancreas	V4283	0.1358	0.0026
Gastrostomy status	V441	0.02576	0.2534
Ileostomy status	V442	-0.07135	0.0349
Colostomy status	V443	0.01882	0.4186
Urinostomy status NEC	V446	0.27221	<.0001
Respirator depend status	V4611	0.08244	<.0001
Status amput othr toe(s)	V4972	-0.02421	0.1067
Status amput below knee	V4975	0.14259	<.0001
Status amput above knee	V4976	0.09281	<.0001
Atten to gastrostomy	V551	-0.05311	0.0197
Long-term use of insulin	V5867	0.0585	<.0001
BMI 40.0-44.9, adult	V8541	-0.03968	0.0375
Less than 6 months of Medicare eligible claims in the previous calendar year		0.53332	<.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 multicollinearity among covariates, likely resulting in some unexpected results in direction of 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 initial and current health condition of the patient in risk adjustment.

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Table 4 presents results for the selected clinical and patient risk factors for the baseline SMR model.

Table 4. Base Model Coefficients, Data Years 2015–2018.

Covariate	Coefficient	P Value^	Hazard Ratio^
Age			
Age (continuous)	-0.07	--	--
Age spline at 14	0.10	--	--
Age spline at 60	0.01	--	--
Race			
White	Reference		
Black	-0.30	--	--
Asian Pacific Islander	-0.37	--	--
Native American	-0.12	--	--
Other	-0.42	--	--
Interaction: Black Race and			
Age (continuous)	0.01	0.77	1.01
Age spline at 14	-0.01	0.68	0.99
Age spline at 60	0.002	0.03	1.00
Interaction: Diabetes as cause of ESRD and			
Asian	0.06	0.001	1.06
Black	-0.08	<.0001	0.92
Native American	-0.01	0.91	1.00
Other	0.14	0.08	1.15
Ethnicity			
Non-Hispanic ethnicity	Reference		
Hispanic	-0.31	--	--
Unknown ethnicity	-0.27	--	--
Interaction: Nonwhite race and:			
Hispanic	0.27	<.0001	1.31
Unknown ethnicity	-0.03	0.67	0.97
Sex: female	-0.08	--	--
Interaction: Black race x female Sex	0.04	<.0001	1.05
Cause of ESRD			
Diabetes	0.19	--	--
Missing	0.13	0.0009	1.14

Covariate	Coefficient	P Value^	Hazard Ratio^
BMI			
BMI < 18.5	0.31	<.0001	1.36
18.5 ⩽ BMI < 25	0.16	<.0001	1.17
25⩽ BMI < 30	0.05	<.0001	1.06
BMI ⩾30	Reference		
Calendar Year			
2015	0.06	<.0001	1.06
2016	0.02	<.0001	1.02
2017	0.004	0.39	1.00
2018	Reference		
Time on ESRD			
0-1 Years	-0.38	--	--
1-2 Years	-0.24	--	--
2-3 Years	-0.18	--	--
3+ Years	Reference		
Interaction: Time on ESRD: < 1 year and:			
Asian	-0.11	<.0001	0.89
Black	0.06	<.0001	1.06
Native American	-0.07	0.17	0.93
Other	-0.03	0.74	0.97
Interaction: Diabetes as cause of ESRD and:			
0-1 Years with ESRD	-0.23	<.0001	0.80
1-2 Years with ESRD	-0.10	<.0001	0.91
2-3 Years with ESRD	-0.03	0.01	0.97
Comorbidities at start of ESRD			
Atherosclerotic heart	0.06	<.0001	1.07
Other cardiac disease	0.08	<.0001	1.09
Congestive heart failure	0.13	<.0001	1.13
Inability to ambulate	0.14	<.0001	1.15
Chronic obstructive pulmonary disease	0.08	<.0001	1.08
Inability to transfer	0.07	<.0001	1.07
Malignant neoplasm, Cancer	0.10	<.0001	1.10
Diabetes	0.04	<.0001	1.04
Peripheral vascular disease	0.06	<.0001	1.06
Cerebrovascular disease, CVA, TIA	0.02	0.01	1.02
Tobacco use (current smoker)	0.15	<.0001	1.16
Alcohol dependence	0.02	0.33	1.02
Drug dependence	0.14	<.0001	1.15
At least one of the comorbidities listed	0.10	<.0001	1.11
No Medical Evidence (CMS-2728)	0.43	<.0001	1.54

Covariate	Coefficient	P Value^	Hazard Ratio^
Nursing home during the prior 365 days			
No nursing home care (0 days)	Reference		
Short-term nursing home care (1-89 days)	0.43	<.0001	1.54
Long-term nursing home care (>=90 days)	0.48	<.0001	1.62
Prevalent Comorbidities (condition groups)			
Candidal esophagitis	0.12	<.0001	1.13
Sarcoidosis	0.08	0.01	1.09
Cancer of Liver	0.84	<.0001	2.31
Cancer of Lung	0.69	<.0001	2.00
Cancer of Prostate	0.07	0.002	1.08
Cancer of Bladder	0.37	<.0001	1.45
Cancer of Kidney	0.07	0.003	1.07
Cancer of Bone	0.66	<.0001	1.93
Other Neoplasm	0.31	<.0001	1.36
Non-Hodgkins Lymphoma	0.24	<.0001	1.27
Multiple Myeloma	0.43	<.0001	1.54
Chronic lymphoid leukemia	0.28	<.0001	1.32
Myelodysplastic Syndrome	0.23	<.0001	1.26
Essential Thrombocytopenia	0.13	<.0001	1.14
Diabetes without complications	0.04	<.0001	1.04
Diabetes with complications	0.11	<.0001	1.11
Glucocorticoid deficiency	0.29	<.0001	1.34
Malnutrition / Cachexia	0.28	<.0001	1.32
Disorders of urea cycle metabolism	0.19	<.0001	1.21
Other amyloidosis	0.25	<.0001	1.28
Other specified disorders of metabolism	0.05	0.001	1.05
Morbid Obesity	-0.05	<.0001	0.95
Sickle-cell Anemia	0.45	<.0001	1.56
Pancytopenia	0.19	<.0001	1.21
Neutropenia	0.15	<.0001	1.17
Primary hypercoagulable state	0.05	0.03	1.05
Dementia	0.18	<.0001	1.20
Substance Related Disorders	0.11	0.001	1.12
Miscellaneous Mental Health	0.06	0.28	1.06
Opioid Dependance	0.17	<.0001	1.18
Schizophrenia	0.11	<.0001	1.12
Cerebral degeneration, unspecified	0.04	0.26	1.04
Peripheral autonomic neuropathy in disorders classified elsewhere	0.06	0.09	1.06
Unspecified hereditary and idiopathic peripheral neuropathy	0.03	0.02	1.03
Epilepsy	0.11	<.0001	1.12

Covariate	Coefficient	P Value^	Hazard Ratio^
Bipolar Disorder	0.07	<.0001	1.07
Major depressive affective disorder	0.10	<.0001	1.10
Mood Disorders	0.07	0.02	1.07
Alcohol Related Disorders	0.05	0.01	1.05
Coma	0.31	<.0001	1.36
Cerebral edema	0.25	<.0001	1.28
Critical illness myopathy	-0.16	<.0001	0.86
hypertensive heart disease with heart failure	0.01	0.74	1.01
Myocardial Infarction	0.22	<.0001	1.25
Coronary Atherosclerosis	0.08	<.0001	1. 09
Pulmonary embolism and infarction	0.13	<.0001	1.14
Primary pulmonary hypertension	0.11	0.02	1.12
Pulmonary Heart Disease	0.19	<.0001	1.21
Cardiomyopathy	0.19	<.0001	1.22
Atrioventricular block, complete	0.07	<.001	1.07
Paroxysmal Tachycardia	0.20	<.0001	1.22
Atrial fibrillation	0.21	<.0001	1.24
Atrial flutter	0.05	<.0001	1.05
Sinoatrial node dysfunction	-0.04	<.0001	0.96
Acute Cerebrovascular Disease	0.13	<.0001	1.14
Peripheral and Visceral Atherosclerosis	0.15	<.0001	1.16
Venous Thromboembolism	0.09	<.0001	1.09
Esophageal varices	0.22	<.0001	1.25
Chronic Obstructive Pulmonary Disease	0.13	<.0001	1.14
Asthma	0.03	0.00	1.03
Aspiration Pneumonitis	0.12	<.0001	1.13
Other Lower Respiratory Diseases	0.19	<.0001	1.21
Respiratory Failure	0.18	<.0001	1.20
Enteritis and Ulcerative Colitis	0.06	0.01	1.07
Ileus and Intestinal Obstruction	-0.01	0.36	0.99
Cirrhosis of Liver	0.37	<.0001	1.45
Other Liver Disease	0.27	<.0001	1.31
Pancreatitis	0.17	<.0001	1.18
Chronic Skin Ulcer	0.26	<.0001	1.29
Systemic lupus erythematosus and connective tissue disorders	0.23	<.0001	1.26
Infective arthritis and osteomyelitis	-0.12	<.0001	0.88
Rheumatoid Arthritis	0.08	<.0001	1.08
Pathologic Fracture	0.16	<.0001	1.18
Aseptic Necrosis	0.01	0.86	1.01
Hip and Femur Fracture	-0.02	0.36	0.98

Covariate	Coefficient	P Value^	Hazard Ratio^
Gangrene	0.16	<.0001	1.17
Infection due to urinary catheter	0.002	0.92	1.00
HIV	0.22	<.0001	1.24
Solid Organ Transplant	0.04	0.05	1.04
Gastrostomy status	0.09	<.0001	1.09
Ileostomy / Colostomy Status	0.01	0.41	1.01
Other artificial opening of urinary tract status	0.15	<.0001	1.16
Dependence on respirator, status	0.05	0.03	1.05
Other toe(s) amputation status	0.02	0.15	1.02
Below knee amputation status	0.11	<.0001	1.12
Above knee amputation status	0.14	<.0001	1.16
Long-term (current) use of insulin	0.03	<.0001	1.03
Cancer of Rectum	0.34	<.0001	1.40
Inflammatory polyarthropathy	0.12	0.14	1.13
Sacroiliitis	-0.006	0.95	1.00
Less than 6 Medicare covered months in prior calendar year	0.54	<.0001	1.71

^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 black race means that the effect of female depends on race.

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.**

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Table 4a below presents a sensitivity analysis assessing the inclusion of additional SES measures (the base model already includes race, sex, and ethnicity). It compares coefficients in the original (baseline) SMR model with and without adjustment for the SES measures.

Table 4a. Comparing coefficients between sensitivity models with and without SES adjustors, 2010-2013: Model coefficients

	Baseline SMR			SES-adjusted SMR	
Covariate	Coefficient	P-value		Coefficient	P-value
Medicare coverage*					
Medicare primary + Medicaid	NA	NA		0.01461	0.0044

Covariate	Baseline SMR			SES-adjusted SMR	
	Coefficient	P-value		Coefficient	P-value
Medicare primary + no Medicaid	NA	NA		Reference	-
Medicare secondary/HMO	NA	NA		0.27131	<.0001
Employment status 6 months prior to ESRD					
Unemployed	NA	NA		Reference	-
Employed	NA	NA		0.04617	<.0001
Other/Unknown	NA	NA		0.12512	<.0001
ADI element					
Home value (median)	NA	NA		0.02098	<.0001
Family income (median)	NA	NA		-0.01099	<.0001
Income disparity**	NA	NA		-0.00043	0.8072
Monthly mortgage (median)	NA	NA		-0.01234	0.3707
< 9 years of education (%)	NA	NA		-0.00135	0.0257
No high school diploma (%)	NA	NA		0.00346	<.0001
Home ownership rate (%)	NA	NA		0.00115	<.0001
Families below the poverty level (%)	NA	NA		0.00149	0.0093
Gross rent (median)	NA	NA		-0.03188	0.0617
Single-parent households with children <18 (%)	NA	NA		-0.00172	<.0001
Unemployment rate (%)	NA	NA		0.00194	0.1061
Comorbidities at start of ESRD					
At least one of the comorbidities listed below	0.15783	<.0001		0.15872	<.0001
Atherosclerotic heart disease	0.04559	<.0001		0.04497	<.0001
Other cardiac disease	0.06736	<.0001		0.06610	<.0001
Diabetes***	0.01596	0.0389		0.00909	0.2402
Congestive heart failure	0.12221	<.0001		0.12053	<.0001
Inability to ambulate	0.14953	<.0001		0.14973	<.0001
Chronic obstructive pulmonary disease	0.07399	<.0001		0.07118	<.0001
Inability to transfer	0.11727	<.0001		0.11738	<.0001
Malignant neoplasm, cancer	0.10791	<.0001		0.10938	<.0001
Peripheral vascular disease	0.05252	<.0001		0.05068	<.0001
Cerebrovascular disease, CVA, TIA	0.01484	0.0311		0.01500	0.0295
Tobacco use (current smoker)	0.10783	<.0001		0.10764	<.0001
Alcohol dependence	0.03135	0.0989		0.03031	0.1118
Drug dependence	0.07436	0.0008		0.07526	0.0008
No Medical Evidence (CMS-2728) Form	0.0115	0.7696		0.02392	0.5432
Cause of ESRD					
Diabetes	0.14834	<.0001		0.14697	<.0001
Missing	-0.02574	0.2855		-0.02566	0.2876
Sex: Female	-0.07704	<.0001		-0.07910	<.0001
Age					
Continuous (years)	-0.05786	0.0003		-0.04705	0.0049
Spline at 14 years	0.08753	<.0001		0.07640	<.0001
Spline at 60 years	0.00651	<.0001		0.00687	<.0001
Race: black X age interaction					
Continuous (years)	-0.0371	0.1983		-0.04956	0.0899
Spline at 14 years	0.03412	0.2384		0.04682	0.1104
Spline at 60 years	0.0009396	0.4437		0.00019	0.8764
In nursing home the previous year	0.31026	<.0001		0.30617	<.0001
Incident BMI					
Log BMI (continuous)	-0.48904	<.0001		-0.49342	<.0001
Log BMI (spline at 35)	0.57016	<.0001		0.57780	<.0001
BMI missing	0.14771	<.0001		0.09123	<.0001
Race					

Covariate	Baseline SMR			SES-adjusted SMR	
	Coefficient	P-value		Coefficient	P-value
White	Reference	-		Reference	-
Black	0.31856	0.4275		0.47373	0.2443
Asian/PI	-0.33283	<.0001		-0.32944	<.0001
Native American	-0.12939	0.0015		-0.14447	0.0004
Other/unknown	-0.25062	<.0001		-0.24259	<.0001
Time on ESRD					
< 1 year	-0.18009	<.0001		-0.15762	<.0001
1 to 2 years	-0.21764	<.0001		-0.22296	<.0001
2 to 3 years	-0.17079	<.0001		-0.17220	<.0001
3+ years	Reference	-		Reference	-
Calendar year					
2010	0.1289	<.0001		0.12868	<.0001
2011	0.10334	<.0001		0.10466	<.0001
2012	0.00509	0.3735		0.00637	0.2659
2013	Reference	-		Reference	-
Ethnicity					
Hispanic	-0.31125	<.0001		-0.31963	<.0001
Non-Hispanic ethnicity	Reference	-		Reference	-
Unknown ethnicity	0.09259	0.0082		0.04305	0.2247
Ethnicity X race: nonwhite interaction				0.04305	0.2247
Hispanic ethnicity	0.30208	<.0001		0.29982	<.0001
Unknown ethnicity	0.12773	0.0004		0.13890	0.0001
Race X diabetes as cause of ESRD interaction					
Asian/PI	0.04491	0.0405		0.04655	0.0342
Black	-0.08505	<.0001		-0.08224	<.0001
Native American	-0.00639	0.8865		-0.00422	0.9251
Other	0.10269	0.0266		0.09440	0.0422
Time with ESRD X diabetes as cause of ESRD interaction					
< 1 year	-0.20115	<.0001		-0.20451	<.0001
1 to 2 years	-0.11321	<.0001		-0.11674	<.0001
2 to 3 years	-0.04516	0.0004		-0.04722	0.0002
3+ years	Reference	-		Reference	-
Time on ESRD: < 1 year X race interaction					
Asian/PI	-0.13672	<.0001		-0.12823	<.0001
Black	0.03974	0.0003		0.03854	0.0005
Native American	-0.10883	0.0344		-0.08779	0.0889
Other	0.26902	<.0001		0.28112	<.0001
Time on ESRD: < 1 year X sex: female interaction	0.00915	0.3193		0.01012	0.2716
Sex: female X cause of ESRD: diabetes interaction	-0.00839	0.3009		-0.00766	0.3454
Race: black X sex: female interaction	0.06686	<.0001		0.06466	<.0001

*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 4b presents a sensitivity analysis of inclusion of additional SES measures. It compares coefficients for the prevalent comorbidities that were added into the baseline SMR model to the model with adjustment for additional SES measures.

Table 4b. Comparing coefficients between sensitivity models with and without SDS/SES adjustors, 2010-2013: Prevalent comorbidity coefficients

ICD-9 Description	ICD-9 Code	Baseline SMR		SES-adjusted SMR	
		Coefficient	P-value	Coefficient	P-value
Protein-cal malnutr NOS	2639	0.19068	<.0001	0.18507	<.0001
Aut neuropthy in oth dis	3371	0.02175	0.1983	0.01961	0.2463
Epilep NOS w/o intr epil	34590	0.10419	<.0001	0.09632	<.0001
Cerebral edema	3485	0.21974	<.0001	0.21941	<.0001
Subendo infarct, initial	41071	0.28073	<.0001	0.26653	<.0001
AMI NEC, unspecified	41080	-0.00835	0.8738	-0.00041	0.9938
AMI NOS, unspecified	41090	0.04091	0.0037	0.05808	<.0001
Intermed coronary synd	4111	0.05768	<.0001	0.05824	<.0001
Ac ischemic hrt dis NEC	41189	0.07088	0.0013	0.07115	0.0013
Angina pectoris NEC/NOS	4139	0.00621	0.5314	0.01037	0.2964
Cardiomyopath in oth dis	4258	0.04292	0.0329	0.04335	0.0312
Atriovent block complete	4260	0.15129	<.0001	0.15412	<.0001
Parox ventric tachycard	4271	0.18283	<.0001	0.18208	<.0001
Parox tachycardia NOS	4272	0.07202	0.0747	0.07677	0.0578
Atrial fibrillation	42731	0.24876	<.0001	0.24872	<.0001
Atrial flutter	42732	0.06245	<.0001	0.05850	<.0001
Sinoatrial node dysfunct	42781	-0.04157	<.0001	-0.03410	0.0007
Subdural hemorrhage	4321	0.13039	<.0001	0.13410	<.0001
Stricture of artery	4471	-0.02833	0.0635	-0.02009	0.1885
Paralytic ileus	5601	-0.01047	0.5007	-0.01566	0.3137
Convulsions NEC	78039	0.09323	<.0001	0.09773	<.0001
Gangrene	7854	0.17237	<.0001	0.16491	<.0001
Cachexia	7994	0.33328	<.0001	0.32915	<.0001
Candidal esophagitis	11284	0.21728	<.0001	0.21573	<.0001
Sarcoidosis	135	0.0498	0.1881	0.05122	0.1762
Malignant neopl rectum	1541	0.30273	<.0001	0.30444	<.0001
Mal neo liver, primary	1550	0.36764	<.0001	0.36945	<.0001
Mal neo upper lobe lung	1623	0.27901	<.0001	0.27482	<.0001
Mal neo bronch/lung NOS	1629	0.41213	<.0001	0.41821	<.0001
Malign neopl prostate	185	-0.06496	<.0001	-0.05553	0.0002
Malig neo bladder NOS	1889	0.19631	<.0001	0.20432	<.0001
Malig neopl kidney	1890	-0.04592	0.0198	-0.04201	0.0332
Malign neopl thyroid	193	-0.24613	<.0001	-0.24139	<.0001
Secondary malig neo lung	1970	0.5234	<.0001	0.51907	<.0001
Second malig neo liver	1977	0.90921	<.0001	0.89766	<.0001
Secondary malig neo bone	1985	0.71735	<.0001	0.72095	<.0001
Malignant neoplasm NOS	1991	0.35314	<.0001	0.35642	<.0001
Oth lymp unsp xtrndl org	20280	0.20078	<.0001	0.19980	<.0001
Mult mye w/o achv rmson	20300	0.41084	<.0001	0.41119	<.0001
Ch lym leuk wo achv rmsn	20410	0.37957	<.0001	0.37275	<.0001
Essntial thrombocythemia	23871	0.12789	0.0003	0.12778	0.0003
Low grde myelody syn les	23872	0.15381	0.0017	0.15872	0.0012
Myelodysplastic synd NOS	23875	0.20555	<.0001	0.20504	<.0001
DMII wo cmp nt st uncntr	25000	0.0721	<.0001	0.08063	<.0001
DMII wo cmp uncntrld	25002	-0.01161	0.0705	-0.00322	0.616
DMII keto nt st uncntrld	25010	0.0982	0.0001	0.10744	<.0001
DMII ketoacd uncontrold	25012	0.14458	<.0001	0.13872	<.0001
DMI ketoacd uncontrold	25013	0.28449	<.0001	0.27018	<.0001
DMII hprosmlr uncontrold	25022	0.04571	0.2251	0.03856	0.3067
DMII renl nt st uncntrld	25040	0.03375	<.0001	0.03346	<.0001

ICD-9 Description	ICD-9 Code	Baseline SMR		SES-adjusted SMR	
		Coefficient	P-value	Coefficient	P-value
DMI renl nt st uncntrld	25041	0.07679	<.0001	0.08050	<.0001
DMII ophth nt st uncntrl	25050	0.00575	0.482	0.00487	0.5519
DMI ophth uncntrld	25053	0.0629	0.0443	0.05910	0.0592
DMII neuro nt st uncntrl	25060	-0.00885	0.2742	-0.00427	0.5978
DMI neuro nt st uncntrld	25061	0.03226	0.0203	0.03699	0.0078
DMII neuro uncntrld	25062	-0.004	0.7193	-0.00338	0.7615
DMI neuro uncntrld	25063	0.05321	0.037	0.05173	0.0429
DMII circ nt st uncntrld	25070	-0.01444	0.0857	-0.00987	0.2409
DMI circ nt st uncntrld	25071	-0.02272	0.1652	-0.01331	0.4165
DMII circ uncntrld	25072	0.00435	0.7765	0.00623	0.6842
DMII oth nt st uncntrld	25080	0.12132	<.0001	0.11796	<.0001
DMI oth nt st uncntrld	25081	0.09973	<.0001	0.09945	<.0001
DMII oth uncntrld	25082	0.05006	0.0001	0.04745	0.0003
DMI oth uncntrld	25083	0.14618	<.0001	0.14627	<.0001
Glucocorticoid deficient	25541	0.31984	<.0001	0.31685	<.0001
Oth severe malnutrition	262	0.17484	<.0001	0.16782	<.0001
Dis urea cycle metabol	2706	-0.01549	0.7273	-0.01721	0.6988
Amyloidosis NEC	27739	0.32816	<.0001	0.32030	<.0001
Metabolism disorder NEC	27789	0.13233	0.0078	0.13012	0.0089
Morbid obesity	27801	0.00932	0.3779	0.00456	0.6664
Obesity hypovent synd	27803	-0.02953	0.3107	-0.03330	0.253
Sickle cell disease NOS	28260	0.61472	<.0001	0.60712	<.0001
Antin chemo indcd pancyt	28411	0.39212	<.0001	0.36961	<.0001
Other pancytopenia	28419	0.17159	<.0001	0.16941	<.0001
Neutropenia NOS	28800	0.19529	<.0001	0.19467	<.0001
Drug induced neutropenia	28803	0.29116	<.0001	0.29394	<.0001
Prim hypercoagulable st	28981	0.15977	<.0001	0.15749	<.0001
Senile dementia uncomp	2900	0.07334	<.0001	0.08098	<.0001
Senile delusion	29020	0.1114	0.0105	0.11073	0.011
Vascular dementia,uncomp	29040	0.10829	<.0001	0.11062	<.0001
Drug withdrawal	2920	0.13901	0.0014	0.13186	0.0024
Dementia w/o behav dist	29410	0.10461	<.0001	0.10741	<.0001
Dementia w behavior dist	29411	0.12167	<.0001	0.13003	<.0001
Demen NOS w/o behv dstrb	29420	0.15134	<.0001	0.15265	<.0001
Mental disor NEC oth dis	2948	0.16473	<.0001	0.16480	<.0001
Schizophrenia NOS-unspec	29590	0.16904	<.0001	0.16688	<.0001
Depress psychosis-unspec	29620	0.08783	<.0001	0.08581	<.0001
Recurr depr psychos-unsp	29630	0.04595	0.0459	0.04318	0.0608
Recur depr psych-severe	29633	0.04953	0.0214	0.05826	0.0068
Bipolar disorder NOS	29680	0.03951	0.0718	0.03852	0.0792
Bipolar disorder NEC	29689	0.0765	0.1406	0.07663	0.14
Episodic mood disord NOS	29690	-0.0061	0.8254	-0.00805	0.7711
Alcoh dep NEC/NOS-unspec	30390	0.02262	0.4481	0.01772	0.5525
Alcoh dep NEC/NOS-remiss	30393	-0.0592	0.1194	-0.06103	0.1081
Opioid dependence-unspec	30400	0.23963	<.0001	0.23251	<.0001
Opioid dependence-contin	30401	0.10216	0.0083	0.09609	0.0131
Drug depend NOS-unspec	30490	0.09283	0.0412	0.09262	0.0415
Cereb degeneration NOS	3319	0.10725	<.0001	0.11542	<.0001
Grand mal status	3453	-0.00454	0.8984	-0.00611	0.8635
Psymotr epil w/o int epi	34540	-0.05696	0.1739	-0.05466	0.1919
Anoxic brain damage	3481	0.2873	<.0001	0.28681	<.0001
Idio periph neurpthy NOS	3569	0.03128	0.0003	0.03480	<.0001
Neuropathy in diabetes	3572	0.0258	0.0042	0.01952	0.0303

ICD-9 Description	ICD-9 Code	Baseline SMR		SES-adjusted SMR	
		Coefficient	P-value	Coefficient	P-value
Critical illness myopthy	35981	-0.10948	0.0009	-0.10703	0.0011
Prolif diab retinopathy	36202	-0.056	<.0001	-0.04794	<.0001
Mod nonprolf db retinoph	36205	-0.10539	0.0017	-0.09839	0.0034
Diabetic macular edema	36207	-0.16216	<.0001	-0.15551	<.0001
Hyp ht dis NOS w ht fail	40291	-0.01224	0.5579	-0.00822	0.6944
Pulm embol/infarct NEC	41519	0.02084	0.2221	0.02418	0.1565
Prim pulm hypertension	4160	0.05884	0.0002	0.07312	<.0001
Chr pulmon heart dis NEC	4168	0.1898	<.0001	0.18235	<.0001
Prim cardiomyopathy NEC	4254	0.23084	<.0001	0.22949	<.0001
Crbl emblsm w infrct	43411	0.18777	<.0001	0.18506	<.0001
Crbl art ocl NOS w infrc	43491	0.12749	<.0001	0.13064	<.0001
Aortic atherosclerosis	4400	0.03595	0.0233	0.03158	0.0465
Athscl extrm ntv art NOS	44020	0.02718	0.0013	0.03302	<.0001
Ath ext ntv at w claudct	44021	0.02956	0.0173	0.03543	0.0044
Ath ext ntv at w rst pn	44022	0.0837	<.0001	0.08269	<.0001
Ath ext ntv art ulcrtion	44023	0.05416	<.0001	0.05839	<.0001
Dsct of thoracic aorta	44101	0.11966	0.0452	0.11933	0.0462
Lower extremity aneurysm	4423	0.02375	0.4642	0.02257	0.487
Periph vascular dis NEC	44389	0.02878	0.0596	0.03332	0.0294
Periph vascular dis NOS	4439	0.16444	<.0001	0.16631	<.0001
Deep phlebitis-leg NEC	45119	-0.04641	0.1151	-0.03405	0.2481
Oth inf vena cava thromb	4532	0.30687	<.0001	0.29469	<.0001
Ac DVT/emb prox low ext	45341	0.08701	<.0001	0.07657	0.0001
Ch DVT/embl low ext NOS	45350	0.05663	0.1025	0.05742	0.0979
Ch DVT/embl prox low ext	45351	0.03822	0.3528	0.03670	0.3723
Ch emblsm subclav veins	45375	0.16767	<.0001	0.16457	0.0001
Ac DVT/embl up ext	45382	0.07744	0.0026	0.07820	0.0023
Ac emblsm axillary veins	45384	0.07944	0.049	0.07311	0.0702
Ac embl internl jug vein	45386	0.08068	0.0006	0.07453	0.0016
Ac embl thorac vein NEC	45387	0.07384	0.0288	0.07472	0.0269
Esoph varice oth dis NOS	45621	0.18859	<.0001	0.18789	<.0001
Obs chr bronc w(ac) exac	49121	0.13193	<.0001	0.12911	<.0001
Obs chr bronc w ac bronc	49122	-0.0088	0.5824	-0.00995	0.5339
Emphysema NEC	4928	0.07809	<.0001	0.08582	<.0001
Chronic obst asthma NOS	49320	0.01834	0.1388	0.01747	0.1583
Ch obst asth w (ac) exac	49322	0.01286	0.4885	0.01140	0.5388
Bronchiectas w/o ac exac	4940	0.03515	0.3221	0.04016	0.2583
Chr airway obstruct NEC	496	0.16266	<.0001	0.16095	<.0001
Food/vomit pneumonitis	5070	0.1607	<.0001	0.15828	<.0001
Postinflam pulm fibrosis	515	0.15118	<.0001	0.15382	<.0001
Lung involv in oth dis	5178	0.15956	0.0088	0.15551	0.0108
Ac resp flr fol trma/srg	51851	0.02845	0.355	0.02576	0.4026
Ot pul insuf fol trm/srg	51852	-0.06297	0.3178	-0.05118	0.4168
Other pulmonary insuff	51882	0.09857	<.0001	0.10648	<.0001
Chronic respiratory fail	51883	0.11434	<.0001	0.11153	<.0001
Acute & chronc resp fail	51884	0.12628	<.0001	0.11971	<.0001
Gastrostomy comp - mech	53642	0.15365	<.0001	0.15654	<.0001
Regional enteritis NOS	5559	0.12126	0.0002	0.11992	0.0002
Ulceratve colitis unspcf	5569	0.02044	0.5561	0.02618	0.4509
Chr vasc insuff intest	5571	0.13302	<.0001	0.12928	<.0001
Fecal impaction	56032	0.04821	0.1281	0.04974	0.1165
Intestinal obstruct NOS	5609	0.08494	<.0001	0.08695	<.0001
Alcohol cirrhosis liver	5712	0.15572	<.0001	0.15281	<.0001

ICD-9 Description	ICD-9 Code	Baseline SMR		SES-adjusted SMR	
		Coefficient	P-value	Coefficient	P-value
Cirrhosis of liver NOS	5715	0.41697	<.0001	0.41478	<.0001
Hepatic encephalopathy	5722	0.31225	<.0001	0.30759	<.0001
Portal hypertension	5723	0.22903	<.0001	0.22448	<.0001
Oth sequela, chr liv dis	5728	0.2376	<.0001	0.23753	<.0001
Chronic pancreatitis	5771	0.17966	<.0001	0.17399	<.0001
Pressure ulcer, low back	70703	0.22465	<.0001	0.22107	<.0001
Pressure ulcer, hip	70704	0.24053	<.0001	0.24067	<.0001
Pressure ulcer, buttock	70705	0.09838	<.0001	0.10478	<.0001
Ulcer of lower limb NOS	70710	0.09412	<.0001	0.09780	<.0001
Ulcer other part of foot	70715	0.08756	<.0001	0.08939	<.0001
Ulcer oth part low limb	70719	0.16587	<.0001	0.16417	<.0001
Chronic skin ulcer NEC	7078	0.14188	<.0001	0.14378	<.0001
Syst lupus erythematosus	7100	0.19554	<.0001	0.19217	<.0001
Systemic sclerosis	7101	0.39484	<.0001	0.39577	<.0001
Pyogen arthritis-unspec	71100	-0.04327	0.3753	-0.03074	0.5285
Pyogen arthritis-l/leg	71106	0.02859	0.4542	0.02339	0.5399
Rheumatoid arthritis	7140	0.0896	<.0001	0.08839	<.0001
Inflamm polyarthrop NOS	7149	-0.02268	0.6699	-0.01212	0.8198
Sacroiliitis NEC	7202	0.04558	0.2878	0.05254	0.221
Ac osteomyelitis-unspec	73000	-0.04987	0.131	-0.04126	0.2117
Ac osteomyelitis-ankle	73007	-0.08917	<.0001	-0.08530	<.0001
Ac osteomyelitis NEC	73008	-0.03235	0.307	-0.02967	0.3489
Osteomyelitis NOS-hand	73024	0.24478	<.0001	0.25059	<.0001
Osteomyelitis NOS-ankle	73027	-0.12149	<.0001	-0.12727	<.0001
Path fx vertebrae	73313	0.22531	<.0001	0.22783	<.0001
Aseptic necrosis femur	73342	0.10754	0.0188	0.10703	0.0194
Asept necrosis bone NEC	73349	0.15539	0.006	0.15596	0.0058
Coma	78001	0.21242	<.0001	0.21663	<.0001
Fracture of pubis-closed	8082	0.11422	0.0001	0.11024	0.0002
Pelvic fracture NOS-clos	8088	0.05103	0.1367	0.06459	0.0593
Fx femur intrcaps NEC-cl	82009	-0.00952	0.7647	-0.01431	0.6523
Fx neck of femur NOS-cl	8208	0.04397	0.0051	0.05341	0.0007
Fx femur NOS-closed	82100	-0.02136	0.4055	-0.01357	0.5972
Amput below knee, unilat	8970	-0.09002	<.0001	-0.08001	<.0001
Amputat bk, unilat-compl	8971	-0.01234	0.7926	-0.00414	0.9299
Amput above knee, unilat	8972	-0.11732	<.0001	-0.11178	<.0001
Amputat leg, unilat NOS	8974	-0.08497	0.064	-0.07749	0.0912
React-indwell urin cath	99664	0.05432	0.0555	0.05003	0.0778
Compl heart transplant	99683	0.09947	0.1582	0.10317	0.1429
Asymp hiv infectn status	V08	0.46221	<.0001	0.45689	<.0001
Heart transplant status	V421	0.19932	0.0002	0.19111	0.0003
Liver transplant status	V427	0.03733	0.2656	0.03314	0.3237
Trnspl status-pancreas	V4283	0.1358	0.0026	0.12049	0.0076
Gastrostomy status	V441	0.02576	0.2534	0.02395	0.288
Ileostomy status	V442	-0.07135	0.0349	-0.07559	0.0254
Colostomy status	V443	0.01882	0.4186	0.01801	0.4392
Urinostomy status NEC	V446	0.27221	<.0001	0.26452	<.0001
Respirator depend status	V4611	0.08244	<.0001	0.08209	<.0001
Status amput othr toe(s)	V4972	-0.02421	0.1067	-0.02797	0.0622
Status amput below knee	V4975	0.14259	<.0001	0.13869	<.0001
Status amput above knee	V4976	0.09281	<.0001	0.09153	<.0001
Atten to gastrostomy	V551	-0.05311	0.0197	-0.04863	0.0326
Long-term use of insulin	V5867	0.0585	<.0001	0.05185	<.0001

ICD-9 Description	ICD-9 Code	Baseline SMR		SES-adjusted SMR	
		Coefficient	P-value	Coefficient	P-value
BMI 40.0-44.9, adult	V8541	-0.03968	0.0375	-0.04271	0.0252
Less than 6 months of Medicare eligible claims in the previous calendar year	—	0.53332	<.0001	0.44731	<.0001

Patient-level SDS: Compared with men, women were less likely to die (OR=0.92; p<0.01). Patients of Asian/PI, Native American and Other/unknown race, respectively, all had lower odds of mortality compared to the reference group of white patients (OR=0.72, p<0.01; OR= 0.87, p<0.01; OR=0.78, p<0.01). Mortality in Black patients was not significantly different from the reference group. We did find that Hispanic patients had lower odds of mortality (OR=0.73, p<0.01), consistent with observations in previous studies

Patient-level SES: Patients employed prior to ESRD incidence, and patients with unknown employment status (OR=1.13, p<0.01) had higher odds of mortality (OR=1.05; p<0.01) compared to unemployed patients. Note that for employment categories, the "Other/Unknown" category represents a diverse patient group with regard to SES, such as students, homemakers and those who are retired. Compared with Medicare-only patients, patients with both Medicare and Medicaid (OR=1.01; p=.004) and patients with Medicare as secondary/Medicare HMO (OR=1.31; p<0.01) had higher odds of mortality. The result for dually eligible patients having higher mortality is consistent with the hypothesis that this insurance category, on average, represents an at-risk group, but further examination is needed for the higher odds of mortality for patients with Medicare as secondary payer or HMO. It is possible that these patients represent a larger portion of incident ESRD patients, which has a known higher mortality in the first year of ESRD.

Area-level SES: Areas with high measures of deprivation are likely to have higher mortality as demonstrated in the literature for the general population as well as for the ESRD population. In general, we observed small effects on odds of mortality, in the expected direction, for most of the individual indicators of area deprivation, with several achieving statistical significance. This included a low percentage of the population with a high school diploma. The percentage of single parent households with children <18 years however had a slightly negative impact on odds of mortality. But this could be attributed to being a generally a younger population that qualifies for social assistance and Medicaid. Overall the results provide nominal support for the postulated relationships between indicators of area-level deprivation and mortality. Further analysis would need to be conducted to determine any differences in impact when combining these factors into a composite measure of area-level deprivation. But this will be subject to data availability.

The figure below shows the correlation between facility SMRs with and without adjustment for patient and area-level SES.

Figure 1. Correlation between SMR with and without SES adjustment, 2010-2013

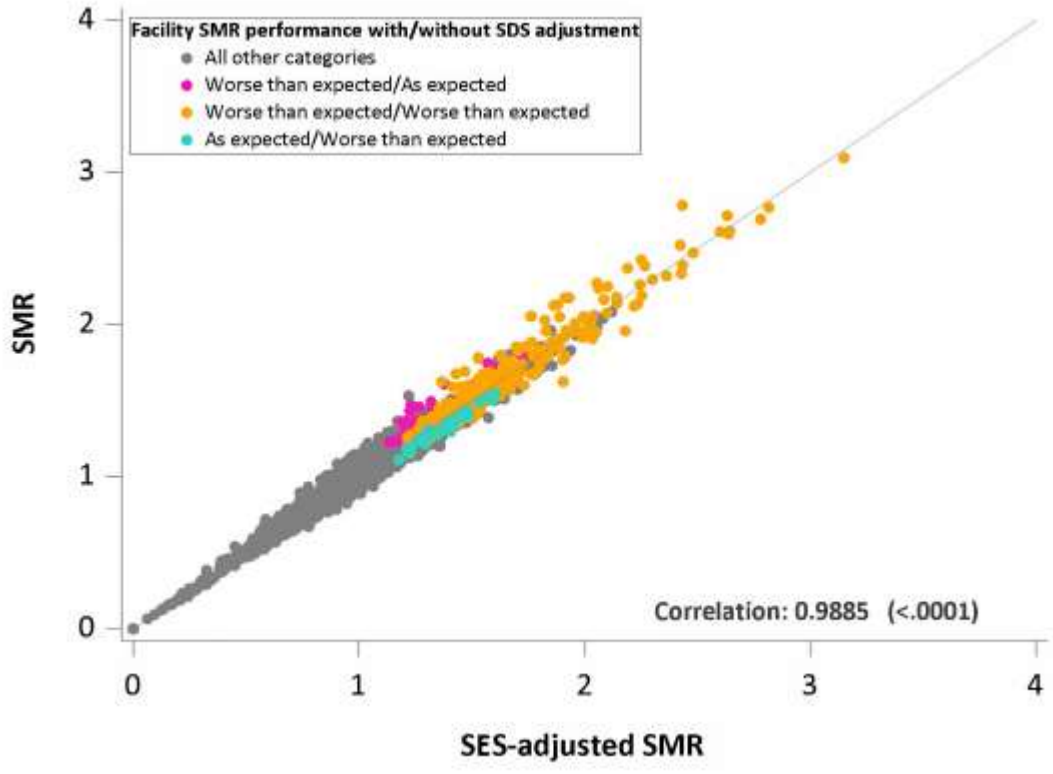

Table 5. Flagging rates, by model with and without all SES adjustors: 2010-2013

	With SES			
Without SDS *(current model)*	Better than Expected	As Expected	Worse than Expected	**Total**
Better than Expected	400	57	0	**457 (7.7%)**
As Expected	52	4938	33	**5023 (84.7%)**
Worse than Expected	0	57	393	**450 (7.6%)**
Total	**452 (7.6%)**	**5052 (85.2%)**	**426 (7.2%)**	—

After adjustment for patient and area-level SES, 199 facilities (3.4%) changed performance categories. Ninety (1.5%) facilities were down-graded, and 109 (1.8%) were upgraded.

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Table 3 below presents a sensitivity analysis assessing the inclusion of additional measure of SES/SDS (the base model already includes race, sex, and ethnicity). It compares coefficients in the original (baseline) SMR model to a model with adjustment for a set of SES measures.

Table 5. Comparing coefficients between sensitivity models with and without SES adjustors, 2015-2018: Model coefficients

	Baseline SMR			SDS/SES Adjusted SMR		
Covariate	**Coefficient**	**P Value**	**Hazard Ratio**	**Coefficient**	**P Value^**	**Hazard Ratio^**
Employment status						
Employed	--	--	--	Reference		
Unemployed	--	--	--	0.12	<.0001	1.13
Other	--	--	--	0.11	<.0001	1.11
Dual Eligible: Eligible for both Medicare and Medicaid	--	--	--	-0.01	0.01	0.99
ADI: ADI score	--	--	--	0.0002	0.22	1.00
Age						
Age (continuous)	-0.07	--	--	-0.07	--	--
Age spline at 14	0.10	--	--	0.09	--	--
Age spline at 60	0.01	--	--	0.01	--	--
Race						
White	Reference			Reference		
Black	-0.30	--	--	-0.29	--	--
Asian Pacific Islander	-0.37	--	--	-0.36	--	--
Native American	-0.12	--	--	-0.12	--	--
Other	-0.42	--	--	-0.42	--	--
Interaction: Black race and						
Age (continuous)	0.01	0.77	1.01	0.01	0.80	1.01
Age spline at 14	-0.01	0.68	0.99	-0.01	0.71	0.99
Age spline at 60	0.002	0.03	1.00	0.002	0.05	1.00
Interaction: Diabetes as cause of ESRD and						
Asian	0.06	0.001	1.06	0.06	0.001	1.06
Black	-0.08	<.0001	0.92	-0.08	<.0001	0.92
Native American	-0.01	0.91	1.00	-0.005	0.91	0.995
Other	0.14	0.08	1.15	0.15	0.07	1.16
Ethnicity						
Non-Hispanic ethnicity	Reference			Reference		
Hispanic	-0.31	--	--	-0.31	--	--
Unknown ethnicity	-0.27	--	--	-0.27	--	--
Interaction: Nonwhite race and						
Hispanic	0.27	<.0001	1.31	0.27	<.0001	1.31
Unknown ethnicity	-0.03	0.67	0.97	-0.03	0.65	0.97
Sex: female	-0.08	--	--	-0.08	--	--
Interaction: Black race and female sex	0.04	<.0001	1.05	0.05	<.0001	1.05

	Baseline SMR			SDS/SES Adjusted SMR		
Covariate	**Coefficient**	**P Value**	**Hazard Ratio**	**Coefficient**	**P Value^**	**Hazard Ratio^**
Cause of ESRD						
Diabetes	0.19	--	--	0.19	--	--
Missing	0.13	<.001	1.14	0.14	0.00	1.15
BMI						
BMI < 18.5	0.31	<.0001	1.36	0.31	<.0001	1.36
18.5 ⩽ BMI < 25	0.16	<.0001	1.17	0.16	<.0001	1.17
25⩽ BMI < 30	0.05	<.0001	1.06	0.05	<.0001	1.06
BMI ⩾30	Reference			Reference		
Calendar Year						
2015	0.06	<.0001	1.06	0.06	<.0001	1.06
2016	0.02	<.0001	1.02	0.02	<.0001	1.02
2017	0.004	0.39	1.00	0.00	0.44	1.00
2018	Reference			Reference		
Time on ESRD						
0-1 Years	-0.38	--	--	-0.39	--	--
1-2 Years	-0.24	<.0001	0.79	-0.25	<.0001	0.78
2-3 Years	-0.18	<.0001	0.83	-0.19	<.0001	0.83
3+ Years	Reference			Reference		
Interaction: < 1 year Time on ESRD and						
Asian	-0.11	<.0001	0.89	-0.11	<.0001	0.89
Black	0.06	<.0001	1.06	0.06	<.0001	1.06
Native American	-0.07	0.17	0.93	-0.07	0.16	0.93
Other	-0.03	0.74	0.97	-0.03	0.75	0.97
Interaction: Diabetes as cause of ESRD and						
0-1 Years with ESRD	-0.23	<.0001	0.80	-0.23	<.0001	0.80
1-2 Years with ESRD	-0.10	<.0001	0.91	-0.10	<.0001	0.91
2-3 Years with ESRD	-0.03	0.01	0.97	-0.03	0.01	0.97
Comorbidities at start of ESRD						
Atherosclerotic heart	0.06	<.0001	1.07	0.06	<.0001	1.07
Other cardiac disease	0.08	<.0001	1.09	0.08	<.0001	1.09
Congestive heart failure	0.13	<.0001	1.13	0.12	<.0001	1.13
Inability to ambulate	0.14	<.0001	1.15	0.14	<.0001	1.15
Chronic obstructive pulmonary disease	0.08	<.0001	1.08	0.08	<.0001	1.08
Inability to transfer	0.07	<.0001	1.07	0.07	<.0001	1.07
Malignant neoplasm, Cancer	0.10	<.0001	1.10	0.10	<.0001	1.10
Diabetes	0.04	<.0001	1.04	0.04	<.0001	1.04
Peripheral vascular disease	0.06	<.0001	1.06	0.06	<.0001	1.06

	Baseline SMR			SDS/SES Adjusted SMR		
Covariate	**Coefficient**	**P Value**	**Hazard Ratio**	**Coefficient**	**P Value^**	**Hazard Ratio^**
Cerebrovascular disease, CVA, TIA	0.02	0.01	1.02	0.01	0.06	1.01
Tobacco use (current smoker)	0.15	<.0001	1.16	0.15	<.0001	1.16
Alcohol dependence	0.02	0.33	1.02	0.01	0.42	1.02
Drug dependence	0.14	<.0001	1.15	0.13	<.0001	1.13
At least one of the comorbidities listed	0.10	<.0001	1.11	0.10	<.0001	1.10
No Medical Evidence (CMS-2728)	0.43	<.0001	1.54	0.40	<.0001	1.50
Nursing home during the prior 365 days						
No nursing home care (0 days)	Reference			Reference		
Short-term nursing home care (1-89 days)	0.43	<.0001	1.54	0.43	<.0001	1.53
Long-term nursing home care (>=90 days)	0.48	<.0001	1.62	0.48	<.0001	1.62
Prevalent Comorbidities (condition groups)						
Candidal esophagitis	0.12	<.0001	1.13	0.12	<.0001	1.13
Sarcoidosis	0.08	0.01	1.09	0.08	0.01	1.08
Cancer of Liver	0.84	<.0001	2.31	0.84	<.0001	2.31
Cancer of Lung	0.69	<.0001	2.00	0.69	<.0001	2.00
Cancer of Prostate	0.07	0.002	1.08	0.07	0.001	1.08
Cancer of Bladder	0.37	<.0001	1.45	0.37	<.0001	1.45
Cancer of Kidney	0.07	0.003	1.07	0.07	0.003	1.08
Cancer of Bone	0.66	<.0001	1.93	0.66	<.0001	1.93
Other Neoplasm	0.31	<.0001	1.36	0.31	<.0001	1.36
Non-Hodgkins Lymphoma	0.24	<.0001	1.27	0.24	<.0001	1.27
Multiple Myeloma	0.43	<.0001	1.54	0.43	<.0001	1.55
Chronic lymphoid leukemia	0.28	<.0001	1.32	0.28	<.0001	1.32
Myelodysplastic Syndrome	0.23	<.0001	1.26	0.24	<.0001	1.27
Essential Thrombocytopenia	0.13	<.0001	1.14	0.13	<.0001	1.14
Diabetes without complications	0.04	<.0001	1.04	0.05	<.0001	1.05
Diabetes with complications	0.11	<.0001	1.11	0.11	<.0001	1.11
Glucocorticoid deficiency	0.29	<.0001	1.34	0.29	<.0001	1.34
Malnutrition / Cachexia	0.28	<.0001	1.32	0.28	<.0001	1.32
Disorders of urea cycle metabolism	0.19	<.0001	1.21	0.19	<.0001	1.21
Other amyloidosis	0.25	<.0001	1.28	0.25	<.0001	1.29
Other specified disorders of metabolism	0.05	0.001	1.05	0.04	0.0009	1.05
Morbid Obesity	-0.05	<.0001	0.95	-0.05	<.0001	0.95
Sickle-cell Anemia	0.45	<.0001	1.56	0.44	<.0001	1.56

	Baseline SMR			SDS/SES Adjusted SMR		
Covariate	Coefficient	P Value	Hazard Ratio	Coefficient	P Value^	Hazard Ratio^
Pancytopenia	0.19	<.0001	1.21	0.19	<.0001	1.21
Neutropenia	0.15	<.0001	1.17	0.15	<.0001	1.17
Primary hypercoagulable state	0.05	0.03	1.05	0.05	0.03	1.05
Dementia	0.18	<.0001	1.20	0.18	<.0001	1.20
Substance Related Disorders	0.11	0.001	1.12	0.11	0.001	1.11
Miscellaneous Mental Health	0.06	0.28	1.06	0.06	0.28	1.06
Opioid Dependance	0.17	<.0001	1.18	0.16	<.0001	1.18
Schizophrenia	0.11	<.0001	1.12	0.11	<.0001	1.11
Cerebral degeneration, unspecified	0.04	0.26	1.04	0.04	0.25	1.05
Peripheral autonomic neuropathy in disorders classified elsewhere	0.06	0.09	1.06	0.06	0.09	1.06
Unspecified hereditary and idiopathic peripheral neuropathy	0.03	0.02	1.03	0.03	0.02	1.03
Epilepsy	0.11	<.0001	1.12	0.11	<.0001	1.12
Bipolar Disorder	0.07	<.0001	1.07	0.06	0.0002	1.07
Major depressive affective disorder	0.10	<.0001	1.10	0.09	<.0001	1.10
Mood Disorders	0.07	0.02	1.07	0.06	0.02	1.07
Alcohol Related Disorders	0.05	0.01	1.05	0.05	0.02	1.05
Coma	0.31	<.0001	1.36	0.31	<.0001	1.36
Cerebral edema	0.25	<.0001	1.28	0.25	<.0001	1.28
Critical illness myopathy	-0.16	<.0001	0.86	-0.16	<.0001	0.86
hypertensive heart disease with heart failure	0.01	0.74	1.01	0.01	0.74	1.01
Myocardial Infarction	0.22	<.0001	1.25	0.22	<.0001	1.25
Coronary Atherosclerosis	0.08	<.0001	1.09	0.08	<.0001	1.09
pulmonary embolism and infarction	0.13	<.0001	1.14	0.13	<.0001	1.14
Primary pulmonary hypertension	0.11	0.02	1.12	0.11	0.02	1.12
Pulmonary Heart Disease	0.19	<.0001	1.21	0.19	<.0001	1.21
Cardiomyopathy	0.19	<.0001	1.22	0.19	<.0001	1.22
Atrioventricular block, complete	0.07	<.001	1.07	0.07	0.0003	1.07
Paroxysmal Tachycardia	0.20	<.0001	1.22	0.20	<.0001	1.22
Atrial fibrillation	0.21	<.0001	1.24	0.21	<.0001	1.24
Atrial flutter	0.05	<.0001	1.05	0.05	<.0001	1.05
Sinoatrial node dysfunction	-0.04	<.0001	0.96	-0.04	<.0001	0.96
Acute Cerebrovascular Disease	0.13	<.0001	1.14	0.13	<.0001	1.14
Peripheral and Visceral Atherosclerosis	0.15	<.0001	1.16	0.15	<.0001	1.16
Venous Thromboembolism	0.09	<.0001	1.09	0.09	<.0001	1.09
Esophageal varices	0.22	<.0001	1.25	0.23	<.0001	1.25

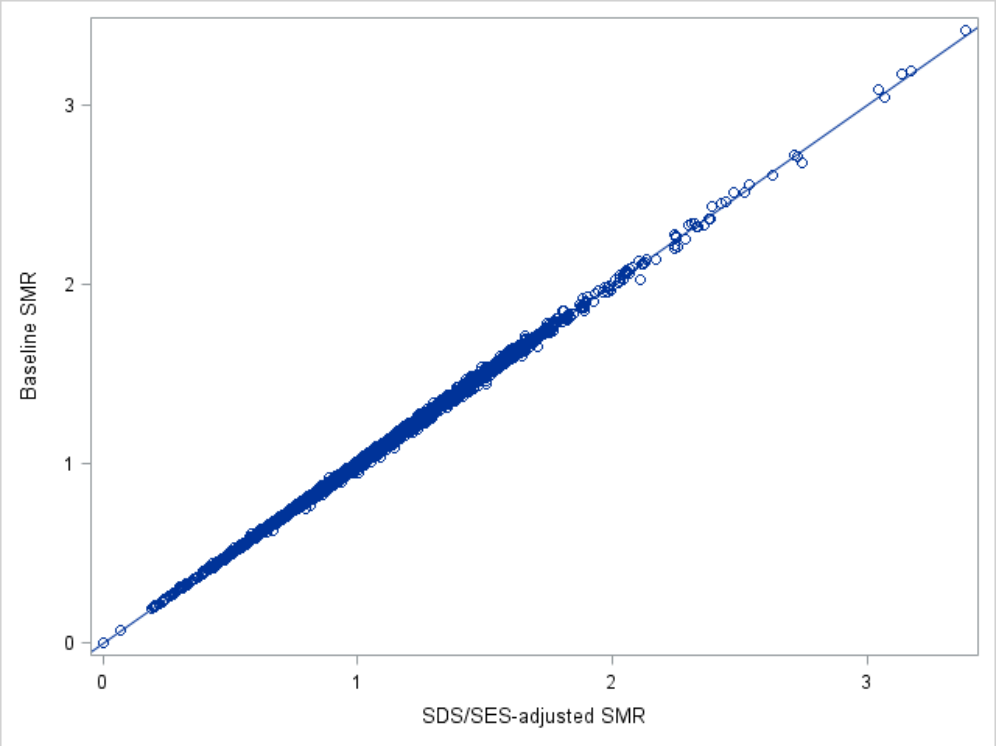
	Baseline SMR			SDS/SES Adjusted SMR		
Covariate	Coefficient	P Value	Hazard Ratio	Coefficient	P Value^	Hazard Ratio^
Chronic Obstructive Pulmonary Disease	0.13	<.0001	1.14	0.13	<.0001	1.14
Asthma	0.03	0.00	1.03	0.03	0.001	1.03
Aspiration Pneumonitis	0.12	<.0001	1.13	0.12	<.0001	1.13
Other Lower Respiratory Diseases	0.19	<.0001	1.21	0.19	<.0001	1.21
Respiratory Failure	0.18	<.0001	1.20	0.18	<.0001	1.20
Enteritis and Ulcerative Colitis	0.06	0.01	1.07	0.06	0.02	1.06
Ileus and Intestinal Obstruction	-0.01	0.36	0.99	-0.01	0.39	0.99
Cirrhosis of Liver	0.37	<.0001	1.45	0.36	<.0001	1.44
Other Liver Disease	0.27	<.0001	1.31	0.27	<.0001	1.31
Pancreatitis	0.17	<.0001	1.18	0.16	<.0001	1.18
Chronic Skin Ulcer	0.26	<.0001	1.29	0.26	<.0001	1.29
Systemic lupus erythematosus and connective tissue disorders	0.23	<.0001	1.26	0.23	<.0001	1.25
Infective arthritis and osteomyelitis	-0.12	<.0001	0.88	-0.12	<.0001	0.88
Rheumatoid Arthritis	0.08	<.0001	1.08	0.07	<.0001	1.08
Pathologic Fracture	0.16	<.0001	1.18	0.17	<.0001	1.18
Aseptic Necrosis	0.01	0.86	1.01	0.01	0.86	1.01
Hip and Femur Fracture	-0.02	0.36	0.98	-0.02	0.37	0.98
Gangrene	0.16	<.0001	1.17	0.16	<.0001	1.17
Infection due to urinary catheter	-0.002	0.92	1.00	-0.001	0.95	1.00
HIV	0.22	<.0001	1.24	0.21	<.0001	1.24
Solid Organ Transplant	0.04	0.05	1.04	0.04	0.06	1.04
Gastrostomy status	0.09	<.0001	1.09	0.09	<.0001	1.09
Ileostomy / Colostomy Status	0.01	0.41	1.01	0.01	0.42	1.01
Other artificial opening of urinary tract status	0.15	<.0001	1.16	0.15	<.0001	1.16
Dependence on respirator, status	0.05	0.03	1.05	0.05	0.03	1.05
Other toe(s) amputation status	0.02	0.15	1.02	0.02	0.17	1.02
Below knee amputation status	0.11	<.0001	1.12	0.11	<.0001	1.12
Above knee amputation status	0.14	<.0001	1.16	0.14	<.0001	1.15
Long-term (current) use of insulin	0.03	<.0001	1.03	0.03	<.0001	1.03
Cancer of Rectum	0.34	<.0001	1.4	0.33	<.0001	1.40
Inflammatory polyarthropathy	0.12	0.14	1.13	0.12	0.14	1.13
Sacroiliitis	-0.006	0.95	1.00	-0.01	0.95	0.99
Less than 6 Medicare covered months in prior calendar year	0.54	<.0001	1.71	0.54	<.0001	1.72

^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 black race means that the effect of female depends on race.

The figure below shows the correlation between facility SMRs with and without adjustment for patient and area-level SES.

Figure 1. Correlation between SMR with and without SES adjustment, 2015-2018



ρ = 0.99959

Table 6. Flagging rates, by model with and without SES adjustors: 2015-2018

	Baseline SMR			
SHR with SES	**Better than Expected**	**As Expected**	**Worse than Expected**	**Total**
Better than Expected	129	6	-	135 (2%)
As Expected	4	6,579	5	6,588(95%)
Worse than Expected	-	5	240	245 (4%)
Total	133 (2%)	6,590 (95%)	245 (4%)	6,969 (95%)

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

These analyses indicate that some patient-level SES variables affect expected death rates, while most patient and area-level SES indicators have at most minimal effect. Furthermore, SMRs with and without adjustment for patient SES and area SES are highly correlated (0.9885, $p<0.0001$), and adjustment for SES shifts facility performance only slightly. This suggests SES does not contribute much to the flagging profiles for facility performance.

Risk adjustment for SES factors would probably reduce the likelihood of penalizing facilities serving a disproportionately larger disadvantaged patient population, resulting in lower quality performance scores and incentive payment reductions for the facility. At the same time, risk adjustment for SES may improve access to care for disadvantaged patients, by guarding against the potential providers may be otherwise less willing to take on these patients because of their higher comorbidity burden. This in effect comes with the risk of effectively holding providers to different (more relaxed) standards for expected patient outcomes, and relatedly may reduce access to the highest quality care for disadvantaged patients. Not adjusting for these sociodemographic and SES factors minimizes the likelihood of reinforcing disparities and counters the notion that different standards in care are acceptable in these populations. In the absence of definitive evidence demonstrating that socioeconomic risk adjustment does not result in differential access to care, we believe that the most appropriate decision is not to risk adjust for socioeconomic factors. Our 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 SMR model we continue to include race, ethnicity, and sex (SDS factors) for risk adjustment based on results from the literature, discussed in section 2b4.3. Patient level SES factors are not included in the final risk adjusted model. 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 SES factors and mortality, 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.

2019 Submission

After adjustment for SDS/SES, 20 facilities (0.29%) changed performance categories. 11 (0.16%) facilities were upgraded, and 9 (0.13%) were down-graded.

Patient race, Hispanic ethnicity, and female sex were associated with lower mortality however the impact of these social risk factors are conditional on their respective relationships with other risk factors captured in the interaction terms in the SMR. Among SES factors only unemployment was associated

with mortality (higher risk). Neither dual eligible status or area level SES deprivation were associated with mortality. Furthermore, SMRs with and without adjustment for patient SES and area SES are highly correlated and adjustment for SES shifts facility performance only slightly. This suggests SES does not contribute much to the flagging profiles for facility performance.

Patient level SES factors are not included in the final risk adjusted model. In the absence of definitive evidence demonstrating that socioeconomic risk adjustment does not result in differential access to care, the most appropriate decision is not to risk adjust for socioeconomic factors. While other studies have shown the association between these patient and area-level SES factors and mortality, 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. 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 SMR model we continue to include race, ethnicity, and sex for risk adjustment based on results from the literature as discussed in section 2b3.3b. Specifically, the direction of the relationship between race, ethnicity and mortality is inverted relative to the general population, with lower observed mortality in blacks and Hispanics on chronic dialysis compared to whites and non-Hispanics (Kalbfleisch et al 2015). As noted by Kalbfleisch et al (2015), the intent of the measure is to clearly identify facilities whose outcomes are below the national average. With this approach, the adjusted analyses that include race, Hispanic ethnicity, and sex do not obscure disparities in health care, but tend to clarify potential disparities. Without adjustment, we may erroneously conclude that those facilities with a high concentration of these generally underserved population have outcomes better than the national norm. Females in the general population have lower mortality rates (CDC National Vital Statistics Reports, 2012) than males. Adjustment for sex allows for a fair comparison between dialysis facilities with patient populations that have a different mix of males and females.

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

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

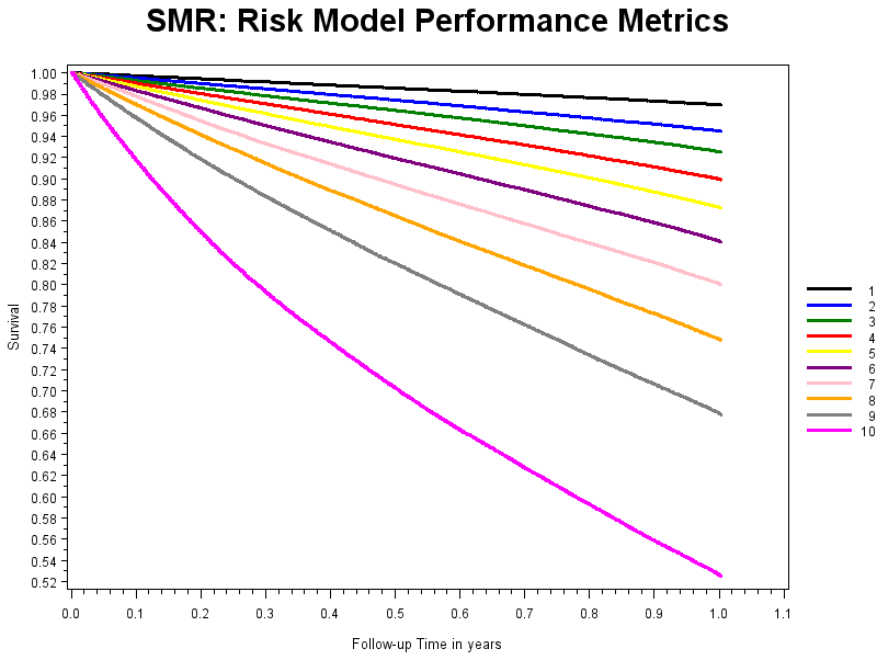
In this model, the C-Statistic =0.724 which suggests good predictive ability of the risk model.

2019 Submission
In this model, the C-Statistic =0.72 which suggests good predictive ability of the risk model.

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

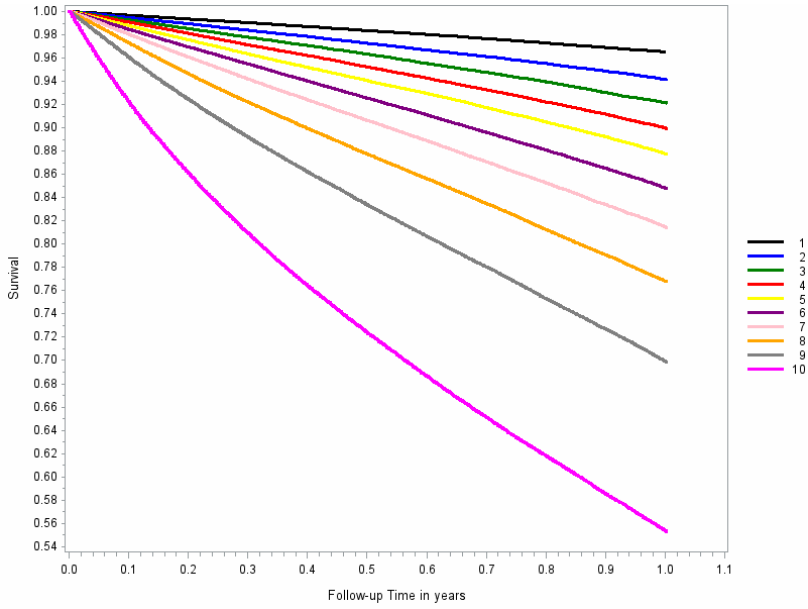
2b3.8. Statistical Risk Model Calibration – Risk decile plots or calibration curves:

2016 Submission
Figure2. Decile plot for SMR



2019 Submission

Figure 2. Decile plot for SMR



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

Figure 2 is the decile plot showing estimates of cumulative rates by years. The 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 the best survival rates). The absolute differences between the groups is also large with survival at one year ranging from 96% for those patients predicted to have the lowest mortality rates (group 1) down to 60% for those predicted to have the lowest rates of survival (group 10).

2019 Submission

The interpretation from the previous submission remains accurate for the updated results in this submission.

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

The p-value for a given facility is a measure of the strength of the evidence against the hypothesis that the mortality rate for this facility is identical to that seen nationally overall, having adjusted for the patient mix. Thus, the p-value is the probability that the facility's SMR would deviate from 1.00 (national rate) by at least as much as the facility's observed SMR. In practice, the p-value is computed using a Poisson approximation under which the distribution of the number of deaths in the facility is Poisson with a mean value equal to E, the expected number of deaths as computed from the Cox model. Accordingly, if the observed number, O, is greater than E, then p-value = 2 * Pr(X>=O) where X has a Poisson distribution with mean E. Similarly, if O<E, the p-value = 2 * Pr(X <=O) where X has a Poisson distribution with mean E.

2019 Submission

The p-value for a given facility is a measure of the strength of the evidence against the hypothesis that the mortality rate for this facility is identical to that seen nationally overall, having adjusted for the patient mix. Thus, the p-value is the probability that the facility's SMR would deviate from 1.00 (national rate) by at least as much as the facility's observed SMR. In practice, the p-value is computed using a Poisson approximation under which the distribution of the number of deaths in the facility is Poisson with a mean value equal to E, the expected number of deaths as computed from the Cox model. Accordingly, if the observed number, O, is greater than E, then the mid p-value = Pr(X>=O)+ Pr(X>O) where X has a Poisson distribution with mean E. Similarly, if O<E, the mid p-value = Pr(X <=O)+ Pr(X<O) where X has a Poisson distribution with mean E.

To address the problem of simultaneously monitoring a large number of facilities and to take account of the intrinsic unexplained variation among facilities, we used the approach described in Kalbfleisch and Wolfe (2013). This method is based on the empirical null as described in Efron (2004, 2007). The p-value for each facility is converted to a Z-score, stratified into four groups based on patient-years within each facility. The empirical null corresponds to a normal curve that is fitted to the center of each Z-score histograms using a robust M-estimation method. The standard deviation of empirical null distribution is then used for a reference distribution (with mean 0) to identify outlier facilities. This method aims to separate underlying intrinsic variation in facility outcomes from variation that might be attributed to poor (or excellent) care.

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 6. Number and percentage of facilities by classification of the 2013 SMR. Categories stratified by facility size.

Number of patients	Better than expected	As expected	Worse than expected
<=45	0.48% (26)	21.09% (1141)	0.54% (29)
45-85	1.09% (59)	37.93% (2052)	1.50% (81)
>=86	2.03% (110)	33.48% (1811)	1.87% (101)

Table 7. Number and percentage of facilities by classification of the 2010-2013 SMR. Categories stratified by facility size.

Number of patients	Better than expected	As expected	Worse than expected
<=135	0.69% (41)	19.05% (1131)	1.18% (70)
136-305	2.21% (131)	34.38% (2041)	2.49% (148)
>=306	4.80 % (285)	31.28% (1857)	3.91% (232)

2019 Submission

Table 7. Number and percentage of facilities by classification of the 2015-2018 SMR (based on two-tailed empirical null p-value less than 5%).

Better than Expected	As Expected	Worse than Expected
133 (1.91%)	6,591 (94.58%)	245 (3.52%)

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

Facilities are flagged if they have outcomes that are extreme when compared to the variation in national death rates adjusted for patient case-mix.

For both the one-year SMR and four-year SMR, a majority of facilities had mortality that was “As Expected.” Overall, for the 2013 SMR, approximately 3.6% of facilities had SMR that was “Better than expected,” while 3.9% of all facilities had SMR that was “Worse than expected.” Across all facilities, for the 2010-2013 SMR, approximately 7.7% of facilities had a SMR that was “Better than expected,” while 7.6% of facilities had a SMR that was “Worse than expected.”

2019 Submission

The effective sample size in the four-year SMR is larger than the one-year SMR. 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 mortality. 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. Across all facilities, for the 2015-2018 SMR, approximately 1.91% of facilities had a SMR that was "Better than expected," while 3.52% of facilities had a SMR that was "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 SMR 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, SMR 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 of paid 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.

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 minimum dialysis paid 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 SMR 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. 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 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 8) 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 8. 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)
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 9. Percent Missing Data

	Missing
BMI	1.85%
Cause of ESRD	0.8%
Missing 2728	1.16%
Less than 6 Medicare covered months in the 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

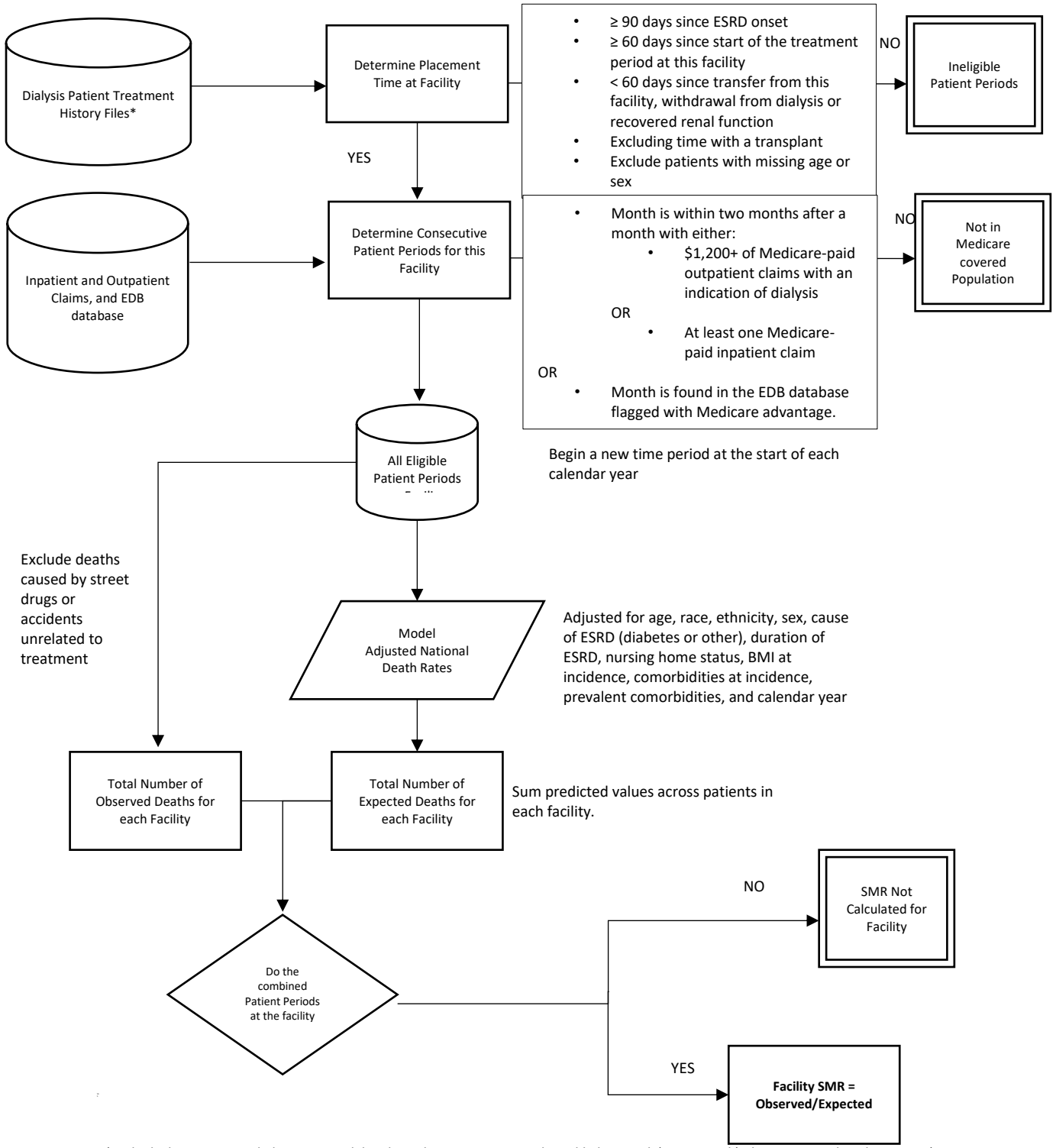
percentage of patients with less than 6 months of eligible Medicare covered months is 21%, meaning we cannot ascertain prevalent comorbidities for these patients. This is a limitation of relying on Medicare claims for ascertaining comorbidities. However, we mitigate bias in measure performance scores 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. 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 form 2728, and missing cause of ESRD. 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 Flow Chart

Standardized Mortality Ratio: The ratio of observed to expected deaths
Numerator Statement: Number of deaths observed
Denominator Statement: Number of deaths 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.