

NATIONAL QUALITY FORUM

Measure Submission and Evaluation Worksheet 5.0

This form contains the information submitted by measure developers/stewards, organized according to NQF's measure evaluation criteria and process. The evaluation criteria, evaluation guidance documents, and a blank online submission form are available on the [submitting standards web page](#).

NQF #: 0369 NQF Project: Renal Endorsement Maintenance 2011
(for Endorsement Maintenance Review) Original Endorsement Date: May 15, 2008 Most Recent Endorsement Date: May 15, 2008
BRIEF MEASURE INFORMATION
De.1 Measure Title: Dialysis Facility Risk-adjusted Standardized Mortality Ratio
Co.1.1 Measure Steward: Centers for Medicare & Medicaid Services
De.2 Brief Description of Measure: Risk-adjusted standardized mortality ratio for dialysis facility patients.
2a1.1 Numerator Statement: Number of deaths among eligible patients at the facility during the 4-year time period.
2a1.4 Denominator Statement: Number of deaths that would be expected among eligible dialysis patients at the facility during the 4-year time period, given the mortality rate is at the national average and the patient mix at the facility.
2a1.8 Denominator Exclusions: N/A
1.1 Measure Type: Outcome 2a1. 25-26 Data Source: Administrative claims 2a1.33 Level of Analysis: Facility
1.2-1.4 Is this measure paired with another measure? No
De.3 If included in a composite, please identify the composite measure (<i>title and NQF number if endorsed</i>): N/A

STAFF NOTES (<i>issues or questions regarding any criteria</i>)
Comments on Conditions for Consideration:
Is the measure untested? Yes <input type="checkbox"/> No <input type="checkbox"/> If untested, explain how it meets criteria for consideration for time-limited endorsement:
1a. Specific national health goal/priority identified by DHHS or NPP addressed by the measure (<i>check De.5</i>): 5. Similar/related endorsed or submitted measures (<i>check 5.1</i>): Other Criteria:
Staff Reviewer Name(s):

1. IMPACT, OPPORTUNITY, EVIDENCE - IMPORTANCE TO MEASURE AND REPORT
Importance to Measure and Report is a threshold criterion that must be met in order to recommend a measure for endorsement. All three subcriteria must be met to pass this criterion. See guidance on evidence . <i>Measures must be judged to be important to measure and report in order to be evaluated against the remaining criteria. (evaluation criteria)</i>
1a. High Impact: H <input type="checkbox"/> M <input type="checkbox"/> L <input type="checkbox"/> I <input type="checkbox"/> (<i>The measure directly addresses a specific national health goal/priority identified by DHHS or NPP, or some other high impact</i>)

aspect of healthcare.)

De.4 Subject/Topic Areas (Check all the areas that apply): Renal, Renal : End Stage Renal Disease (ESRD)

De.5 Cross Cutting Areas (Check all the areas that apply): Population Health

1a.1 Demonstrated High Impact Aspect of Healthcare: Affects large numbers, Patient/societal consequences of poor quality, Severity of illness

1a.2 If "Other," please describe:

1a.3 Summary of Evidence of High Impact (Provide epidemiologic or resource use data):

Epidemiological: At the end of 2007 there were 527,283 patients being dialyzed of which 111,000 were new (incident) End Stage Renal Disease (ESRD) patients (USRDS 2009). In 2009, the ESRD mortality rate was nearly 7 times the Medicare population (USRDS 2009). ESRD mortality in the US was 33% higher than in Europe (Goodkin, 2004), so this outcome is important to patients. The components of unexplained or unexpected mortality that are actionable and associated with treatment and overall management of ESRD and other conditions are important to identify.

Financial: Patient health care for ESRD patients carries high costs associated with mortality. Inefficient and inappropriate management of all aspects of patient ESRD care carries a high costs for both providers and payers. In 2007, total Medicare costs for the ESRD program were \$24 billion (a 6% increase from 2006) (USRDS 2009).

Policy: This measure has been in use in the Dialysis Facility Reports (formerly Unit-Specific Reports) since 1995 and on the Dialysis Facility Compare (DFC) web site (www.medicare.gov) since 2001, when the Balanced Budget Act (1997) required a system to measure and report the quality of dialysis services under Medicare.

The Dialysis Facility Reports are used by the dialysis facilities and ESRD Networks for quality improvement, and by ESRD state surveyors for monitoring and surveillance. The Standardized Mortality Ratio (SMR) in particular 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.

1a.4 Citations for Evidence of High Impact cited in 1a.3: U S Renal Data System, USRDS 2009 Annual Data Report: Atlas of Chronic Kidney Disease and End-Stage Renal Disease in the United States, National Institutes of Health, National Institute of Diabetes and Digestive and Kidney Diseases, Bethesda, MD, 2009.

Goodkin DA, Young EW, Kurokawa K, Prutz K-G, Levin NW: Mortality among hemodialysis patients in Europe, Japan, and the United States: Case-mix effects. *Am J Kidney Dis* 2004; 44[Suppl 2]: S16-S21.

1b. Opportunity for Improvement: H M L I

(There is a demonstrated performance gap - variability or overall less than optimal performance)

1b.1 Briefly explain the benefits (improvements in quality) envisioned by use of this measure:

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. A high SMR also promotes quality reviews within a facility.

1b.2 Summary of Data Demonstrating Performance Gap (Variation or overall less than optimal performance across providers):

[For **Maintenance** – Descriptive statistics for performance results for this measure - distribution of scores for measured entities by quartile/decile, mean, median, SD, min, max, etc.]

The Standardized Mortality Ratio varies widely across facilities. For example, for the period 2006 – 2009, the SMR varied from 0.0 to 4.9. The mean value was 1.0 and the standard deviation was 0.3.

1b.3 Citations for Data on Performance Gap: [For **Maintenance** – Description of the data or sample for measure results reported in 1b.2 including number of measured entities; number of patients; dates of data; if a sample, characteristics of the entities included]

Annual Dialysis Facility Reports for ESRD facilities, <http://dialysisreports.org>

1b.4 Summary of Data on Disparities by Population Group: [For **Maintenance** –Descriptive statistics for performance results for this measure by population group]

Investigations of the SMR by racial, ethnic and gender groups indicate relatively little variation and no substantial disparities among the groups.

1b.5 Citations for Data on Disparities Cited in 1b.4: [*For Maintenance – Description of the data or sample for measure results reported in 1b.4 including number of measured entities; number of patients; dates of data; if a sample, characteristics of the entities included*]

N/A

1c. Evidence (*Measure focus is a health outcome OR meets the criteria for quantity, quality, consistency of the body of evidence.*)
 Is the measure focus a health outcome? Yes No **If not a health outcome**, rate the body of evidence.

Quantity: H M L I Quality: H M L I Consistency: H M L I

Quantity	Quality	Consistency	Does the measure pass subcriterion1c?
M-H	M-H	M-H	Yes <input type="checkbox"/>
L	M-H	M	Yes <input type="checkbox"/> IF additional research unlikely to change conclusion that benefits to patients outweigh harms: otherwise No <input type="checkbox"/>
M-H	L	M-H	Yes <input type="checkbox"/> IF potential benefits to patients clearly outweigh potential harms: otherwise No <input type="checkbox"/>
L-M-H	L-M-H	L	No <input type="checkbox"/>

Health outcome – rationale supports relationship to at least one healthcare structure, process, intervention, or service

Does the measure pass subcriterion1c?
 Yes IF rationale supports relationship

1c.1 Structure-Process-Outcome Relationship (*Briefly state the measure focus, e.g., health outcome, intermediate clinical outcome, process, structure; then identify the appropriate links, e.g., structure-process-health outcome; process- health outcome; intermediate clinical outcome-health outcome*):

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.

1c.2-3 Type of Evidence (*Check all that apply*):

1c.4 Directness of Evidence to the Specified Measure (*State the central topic, population, and outcomes addressed in the body of evidence and identify any differences from the measure focus and measure target population*):

Mortality is accepted as an important outcome.

1c.5 Quantity of Studies in the Body of Evidence (*Total number of studies, not articles*): N/A

1c.6 Quality of Body of Evidence (*Summarize the certainty or confidence in the estimates of benefits and harms to patients across studies in the body of evidence resulting from study factors. Please address: a) study design/flaws; b) directness/indirectness of the evidence to this measure (e.g., interventions, comparisons, outcomes assessed, population included in the evidence); and c) imprecision/wide confidence intervals due to few patients or events*): N/A

1c.7 Consistency of Results across Studies (*Summarize the consistency of the magnitude and direction of the effect*): N/A

1c.8 Net Benefit (*Provide estimates of effect for benefit/outcome; identify harms addressed and estimates of effect; and net benefit - benefit over harms*):

N/A

1c.9 Grading of Strength/Quality of the Body of Evidence. Has the body of evidence been graded? No

1c.10 If body of evidence graded, identify the entity that graded the evidence including balance of representation and any disclosures regarding bias: N/A

1c.11 System Used for Grading the Body of Evidence: [Other](#)

1c.12 If other, identify and describe the grading scale with definitions: [N/A](#)

1c.13 Grade Assigned to the Body of Evidence: [N/A](#)

1c.14 Summary of Controversy/Contradictory Evidence: [N/A](#)

1c.15 Citations for Evidence other than Guidelines (*Guidelines addressed below*):
[N/A](#)

1c.16 Quote verbatim, the specific guideline recommendation (Including guideline # and/or page #):
[N/A](#)

1c.17 Clinical Practice Guideline Citation: [N/A](#)

1c.18 National Guideline Clearinghouse or other URL: [N/A](#)

1c.19 Grading of Strength of Guideline Recommendation. Has the recommendation been graded? [No](#)

1c.20 If guideline recommendation graded, identify the entity that graded the evidence including balance of representation and any disclosures regarding bias:

1c.21 System Used for Grading the Strength of Guideline Recommendation: [Other](#)

1c.22 If other, identify and describe the grading scale with definitions: [N/A](#)

1c.23 Grade Assigned to the Recommendation: [N/A](#)

1c.24 Rationale for Using this Guideline Over Others: [N/A](#)

Based on the NQF descriptions for rating the evidence, what was the developer's assessment of the quantity, quality, and consistency of the body of evidence?

1c.25 Quantity: [High](#) 1c.26 Quality: [High](#) 1c.27 Consistency: [High](#)

Was the threshold criterion, *Importance to Measure and Report*, met?
(1a & 1b must be rated moderate or high and 1c yes) Yes No
Provide rationale based on specific subcriteria:

For a new measure if the Committee votes NO, then STOP.

For a measure undergoing endorsement maintenance, if the Committee votes NO because of 1b. (no opportunity for improvement), it may be considered for continued endorsement and all criteria need to be evaluated.

2. RELIABILITY & 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. (evaluation criteria)

Measure testing must demonstrate adequate reliability and validity in order to be recommended for endorsement. Testing may be conducted for data elements and/or the computed measure score. Testing information and results should be entered in the appropriate field. Supplemental materials may be referenced or attached in item 2.1. See [guidance on measure testing](#).

S.1 Measure Web Page (*In the future, NQF will require measure stewards to provide a URL link to a web page where current detailed specifications can be obtained*). Do you have a web page where current detailed specifications for this measure can be obtained? [Yes](#)

S.2 If yes, provide web page URL: <http://www.dialysisreports.org/Methodology.aspx>

2a. RELIABILITY. Precise Specifications and Reliability Testing: H M L I

2a1. Precise Measure Specifications. (*The measure specifications precise and unambiguous.*)

2a1.1 Numerator Statement (*Brief, narrative description of the measure focus or what is being measured about the target population, e.g., cases from the target population with the target process, condition, event, or outcome*):

Number of deaths among eligible patients at the facility during the 4-year time period.

2a1.2 Numerator Time Window (*The time period in which the target process, condition, event, or outcome is eligible for inclusion*):

Four years.

2a1.3 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, codes with descriptors, and/or specific data collection items/responses*):

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 four year period is calculated. This count does not include deaths from street drugs or accidents unrelated to treatment: Deaths from these causes varied by facility, with certain facilities (in particular, urban facilities that treated large numbers of male and young patients) reporting large numbers of deaths from these causes and others reporting extremely low numbers (Turenne, 1996). Since these deaths are unlikely to have been due to treatment facility characteristics, they are excluded them from the calculations.

2a1.4 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 4-year time period, given the mortality rate is at the national average and the patient mix at the facility.

2a1.5 Target Population Category (*Check all the populations for which the measure is specified and tested if any*): Adult/Elderly Care, Children's Health

2a1.6 Denominator Time Window (*The time period in which cases are eligible for inclusion*):

Four years.

2a1.7 Denominator Details (*All information required to identify and calculate the target population/denominator such as definitions, codes with descriptors, and/or specific data collection items/responses*):

Denominator Data Collection:

For each patient, the dialysis provider was identified using a combination of the Medicare paid dialysis claims, the Medical Evidence Form, and data from the Standard Information Management System (SIMS) maintained by the ESRD Networks. Treatment facility histories were determined for each patient starting at day 91 of ESRD. Patients are assigned to a facility only once they have been treated there for 60 days. Similarly, patients remain assigned to a facility for 60 days after transfer out of the facility. The continued tabulation of the time at risk for 60 days after transfer out of the facility ensures that the sequelae of treatment at a facility are attributed to that facility, even if the patient is transferred to another facility, such as a hospital-based facility, after the patient's condition worsens. In particular, patients are placed in their initial facility on day 91 of ESRD if they have been treated for at least 60 days at the facility. If on day 91, the patient has been treated at the facility for less than 60 days, the patient is not placed in any facility until they reach day 60 of treatment at a facility. Paid dialysis claims and SIMS data are used to determine that a patient has transferred to another facility. Patient outcomes are attributed to the original facility for 60 days after transfer out. On day 61 after transfer out of a facility, the patient will be placed in the new facility if they have been treated there for 60 days. If the patient has not been treated for 60 days at the new facility (for instance, if there were 2 switches within 60 days of each other), the patient is not placed in any facility until they reach day 60 of treatment at a facility. Patients who receive a transplant are removed from the facility on the day of transplant. Patients who withdraw from dialysis or recover renal function remain assigned to the facility of treatment for 60 days after withdrawal or recovery. Patients are considered lost to follow-up and are removed from the analyses for a facility 1 year after the last evidence of dialysis treatment. In other words, if there is a 1 year period where there are no paid dialysis claims and no SIMS information indicating that a patient is receiving dialysis treatment, the patient is considered lost to follow-up and is not used in the analysis unless dialysis claims or other evidence of dialysis reappears.

Time at Risk

For all patients, time at risk began at the start of the facility treatment period (as described above) and continued until the earliest occurrence of the following: transplant; date of death; end of facility treatment period; or December 31 of the year. A patient may

have been treated at one facility for multiple periods during the same year; patient years at risk include time at risk for all periods of treatment at a facility.

Expected Deaths

The number of expected deaths for each patient is calculated as $-\ln(S_i(t_i))$, where $S_i(t)$ was the survival curve from a Cox model adjusted to the characteristics of patient i , and t_i was the amount of follow-up time (patient years at risk) for that patient during the year (SAS Institute Inc., 2000; Andersen, 1993; Collett, 1994). The Cox model is adjusted for age, sex, race, Hispanic ethnicity, diabetes as a cause of ESRD, nursing home status, duration of ESRD, BMI at incidence, and comorbidities at incidence. In cases where the comorbidities and BMI were missing for a patient, we used the average values of the group of patients with similar characteristics (age, race sex, diabetes). We also control for age-adjusted population death rates by state and race, based on the U.S. population in 2001-2003 (National Center for Health Statistics, 2005). The number of expected deaths for the facility during the 4-year time period is the total expected for all eligible patients at the facility.

2a1.8 Denominator Exclusions (Brief narrative description of exclusions from the target population):

N/A

2a1.9 Denominator Exclusion Details (All information required to identify and calculate exclusions from the denominator such as definitions, codes with descriptors, and/or specific data collection items/responses):

N/A

2a1.10 Stratification Details/Variables (All information required to stratify the measure results including the stratification variables, codes with descriptors, definitions, and/or specific data collection items/responses):

N/A

2a1.11 Risk Adjustment Type (Select type. Provide specifications for risk stratification in 2a1.10 and for statistical model in 2a1.13): **Statistical risk model** 2a1.12 If "Other," please describe:

2a1.13 Statistical Risk Model and Variables (Name the statistical method - e.g., logistic regression and list all the risk factor variables. Note - risk model development should be addressed in 2b4.):

Cox Model (Proportional Hazards Regression Model): The SMR calculation adjusts for patient age, sex, race, Hispanic ethnicity, diabetes as a cause of ESRD, nursing home status, duration of ESRD, BMI at incidence, and comorbidities at incidence, as well as state population death rates by comparing actual to expected deaths at the facility (indirect method of standardization). The number of expected deaths for patients at the facility is based on a Cox model accounting for these patient characteristics.

The Standardized Mortality Ratio measure appears in the Dialysis Facility Report. Sections III and IV of the Guide to the Dialysis Facility Reports (1) and the document Technical Notes (2) on the Standardized Mortality Ratio contain information about the calculation of the SMR (including the risk adjustment methodology). These are available at the Dialysis Facility Reports website: <http://www.dialysisreports.org/Methodology.aspx>

2a1.14-16 Detailed Risk Model Available at Web page URL (or attachment). Include coefficients, equations, codes with descriptors, definitions, and/or specific data collection items/responses. Attach documents only if they are not available on a webpage and keep attached file to 5 MB or less. NQF strongly prefers you make documents available at a Web page URL. Please supply login/password if needed:

URL

<http://www.dialysisreports.org/Methodology.aspx>

2a1.17-18. Type of Score: Ratio

2a1.19 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

2a1.20 Calculation Algorithm/Measure Logic (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; aggregating data; risk adjustment; etc.):

Time at Risk

NQF #0369 Dialysis Facility Risk-adjusted Standardized Mortality Ratio

For all patients, time at risk began at the start of the facility treatment period and continued until the earliest occurrence of the following: transplant; date of death; end of facility treatment period; or December 31 of the year. A patient may have been treated at one facility for multiple periods during the same year; patient years at risk include time at risk for all periods of treatment at a facility. Deaths 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.

Deaths

The number of deaths that occurred among eligible dialysis patients during the four year period is calculated. This count does not include deaths from street drugs or accidents unrelated to treatment. Since these deaths are unlikely to have been due to treatment facility characteristics, they are excluded from the calculation.

Expected Deaths

The number of expected deaths for each patient is calculated as $-\ln(S_i(t_i))$, where $S_i(t_i)$ was the survival curve from a Cox model adjusted to the characteristics of patient i , and t_i was the amount of follow-up time (patient years at risk) for that patient during the year (SAS Institute Inc., 2000; Andersen, 1993; Collett, 1994). The Cox model is adjusted for age, sex, race, Hispanic ethnicity, diabetes as a cause of ESRD, nursing home status, duration of ESRD, BMI at incidence, and comorbidities at incidence (as included on table 7 of DFR). In cases where the comorbidities and BMI were missing for a patient, we used the average values of the group of patients with similar characteristics (age, race sex, diabetes). We also control for age-adjusted population death rates by state and race, based on the most current and relevant U.S. population (National Center for Health Statistics). The number of expected deaths for the facility during the 4-year time period is the total expected for all eligible patients at the facility.

The SMR calculation adjusts for patient age, sex, race, Hispanic ethnicity, diabetes as a cause of ESRD, nursing home status, duration of ESRD, BMI at incidence, and comorbidities at incidence, as well as state population death rates by comparing actual to expected deaths at the facility (indirect method of standardization). The number of expected deaths for patients at the facility is based on a Cox model accounting for these patient characteristics.

The SMR for a facility is the ratio of the total number of observed to the total number of expected deaths during the four year period at the facility.

2a1.21-23 Calculation Algorithm/Measure Logic Diagram URL or attachment:

URL

<http://www.dialysisreports.org/Methodology.aspx>

2a1.24 Sampling (Survey) Methodology. If measure is based on a sample (or survey), provide instructions for obtaining the sample, conducting the survey and guidance on minimum sample size (response rate):

N/A

2a1.25 Data Source (*Check all the sources for which the measure is specified and tested*). If other, please describe:

Administrative claims

2a1.26 Data Source/Data Collection Instrument (*Identify the specific data source/data collection instrument, e.g. name of database, clinical registry, collection instrument, etc.*): Data for the SMR is derived from Program Medical Management and Information System (PMMIS/REMIS), Medicare claims, the Standard Information Management System (SIMS) database maintained by the 18 ESRD Networks, the CMS Annual Facility Survey (CMS Form 2744), the CMS Medical Evidence Form (CMS Form 2728), the Death Notification Form (CMS Form 2746), and the Social Security Death Master File.

2a1.27-29 Data Source/data Collection Instrument Reference Web Page URL or Attachment: URL

<http://www.cms.gov/Manuals/IOM/itemdetail.asp?filterType=none&filterByDID=-99&sortByDID=1&sortOrder=ascending&itemID=CMS018912>

2a1.30-32 Data Dictionary/Code Table Web Page URL or Attachment:

URL

<http://www.cms.gov/Manuals/IOM/itemdetail.asp?filterType=none&filterByDID=-99&sortByDID=1&sortOrder=ascending&itemID=CMS018912&intNumPerPage=10>

2a1.33 Level of Analysis (*Check the levels of analysis for which the measure is specified and tested*): Facility

2a1.34-35 Care Setting (Check all the settings for which the measure is specified and tested): **Dialysis Facility**

2a2. Reliability Testing. (Reliability testing was conducted with appropriate method, scope, and adequate demonstration of reliability.)

2a2.1 Data/Sample (Description of the data or sample including number of measured entities; number of patients; dates of data; if a sample, characteristics of the entities included):

Reliability of the Standardized Mortality Ratio (SMR) was assessed using data on ESRD patients over a four year period of 2006-2009. Data for the SMR are derived from an extensive national ESRD patient database, which is derived from Program Medical Management and Information System (PMMIS/REMIS), Medicare claims, the Standard Information Management System (SIMS) database maintained by the 18 ESRD Networks, the CMS Annual Facility Survey (CMS Form 2744), the CMS Medical Evidence Form (CMS Form 2728), the Death Notification Form (CMS Form 2746), and the Social Security Death Master File. The database is comprehensive for Medicare patients.

2a2.2 Analytic Method (Describe method of reliability testing & rationale):

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.

2a2.3 Testing Results (Reliability statistics, assessment of adequacy in the context of norms for the test conducted):

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.

2b. VALIDITY. Validity, Testing, including all Threats to Validity: H M L I

2b1.1 Describe how the measure specifications (measure focus, target population, and exclusions) are consistent with the evidence cited in support of the measure focus (criterion 1c) and identify any differences from the evidence:

In 1999, the Centers for Medicare & Medicaid Services (CMS) funded the development of dialysis facility-specific measures that could be released in reports to the public for their use in making dialysis treatment choices. An extensive public process was used to select the first set of measures to be publicly reported (Frederick 2002).

In addition, several additional technical meetings have also been held to discuss the technical specifications, reliability and validity of this measure. National Institutes of Health (NIH) and CMS held the Standardized Mortality Ratio Technical Meeting on July 28, 2003 in Bethesda, MD. On September 27, 2004 and February 8, 2006, Research Triangle Institute (RTI), under contract to the CMS, held technical expert panel meetings to review the patient survival quality measure. On September 18-19, 2006, a technical expert panel (TEP) was convened by Arbor Research Collaborative for Health, contractor to CMS, to review and update this measure.

In addition, the Standardized Mortality Ratio (SMR) is used by ESRD state surveyors in conjunction with other standard criteria for prioritizing and selecting facilities to survey and has been found to be predictive of citations in the past (ESRD State Outcomes List).

2b2. Validity Testing. (Validity testing was conducted with appropriate method, scope, and adequate demonstration of validity.)

2b2.1 Data/Sample (Description of the data or sample including number of measured entities; number of patients; dates of data; if a sample, characteristics of the entities included):

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.

2b2.2 Analytic Method (*Describe method of validity testing and rationale; if face validity, describe systematic assessment*): 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 \geq 65%, percent of patients dialyzing with a fistula, and percent of patients dialyzing with a catheter.

2b2.3 Testing Results (*Statistical results, assessment of adequacy in the context of norms for the test conducted; if face validity, describe results of systematic assessment*): 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.

POTENTIAL THREATS TO VALIDITY. (*All potential threats to validity were appropriately tested with adequate results.*)

2b3. Measure Exclusions. (*Exclusions were supported by the clinical evidence in 1c or appropriately tested with results demonstrating the need to specify them.*)

2b3.1 Data/Sample for analysis of exclusions (*Description of the data or sample including number of measured entities; number of patients; dates of data; if a sample, characteristics of the entities included*):
N/A

2b3.2 Analytic Method (*Describe type of analysis and rationale for examining exclusions, including exclusion related to patient preference*):
N/A

2b3.3 Results (*Provide statistical results for analysis of exclusions, e.g., frequency, variability, sensitivity analyses*):
N/A

2b4. Risk Adjustment Strategy. (*For outcome measures, adjustment for differences in case mix (severity) across measured entities was appropriately tested with adequate results.*)

2b4.1 Data/Sample (*Description of the data or sample including number of measured entities; number of patients; dates of data; if a sample, characteristics of the entities included*): Risk Adjustment testing of the Standardized Mortality Ratio (SMR) was conducted using data on ESRD patients over a four year period of 2006-2009. Data for the SMR are derived from an extensive national ESRD patient database, which is derived from Program Medical Management and Information System (PMMIS/REMIS), Medicare claims, the Standard Information Management System (SIMS) database maintained by the 18 ESRD Networks, the CMS Annual Facility Survey (CMS Form 2744), the CMS Medical Evidence Form (CMS Form 2728), the Death Notification Form (CMS Form 2746), and the Social Security Death Master File. The database is comprehensive for Medicare patients.

2b4.2 Analytic Method (*Describe methods and rationale for development and testing of risk model or risk stratification including selection of factors/variables*): To assess the adequacy of the risk model, we calculated the stratified Concordance Index (C-Index) in the survival model, which measures how well the risk model discriminates between different responses, in other words, is the predicted response low for low observed responses and high for high observed responses. In this model, C-Index=0.68 which suggests relatively good predictive ability of the risk model. We also examined the functional form of all continuous variables (Comorbidity Index, log(BMI), and age) in the model through risk decile plots. Risk factor selection: The methods for development of the risk factor models have been published and documented (Wolfe RA et al.

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Using USRDS generated mortality tables to compare local ESRD mortality rates to national rates. *Kidney Int* 1992; 42: 991-96; Wolfe RA et al: New dialysis facility mortality statistics (SMRs) adjust for more patient characteristics. *J Am Soc Nephrol* 2001; 12: A1802). The adjustments included in the model are measured at baseline and are all statistically significant in the model. Two-way interactions were examined and selected for the final model based on both the magnitude and statistical significance of the estimates.

Inclusion of race/ethnicity: While adjustment for race and ethnicity tends to obscure disparities in care for many medical conditions, such adjustment may clarify such disparities in the ESRD setting and failure to adjust for race may obscure those disparities. In a series of analyses spanning several decades, it has been consistently seen that African-American patients have lower death rates than Caucasian patients on dialysis (RR=0.82), with a variety of adjustment models intended to make "all else equal". This difference contributes to the downward trend in mortality seen in Figure 1 for facilities with higher % Black case mix, when the mortality is unadjusted for race (please see the attachment SMR_Risk_Adjustment_Figures_1110.docx). In the unadjusted analysis, facilities with higher % Black have lower mortality, in part because Black patients have lower mortality. That is, facilities with more Black patients have lower death rates, in part due to unadjusted case mix differences, just as facilities treating younger patients would have lower death rates, if age were not adjusted for. The unadjusted analysis does not, and cannot, separate the effect of case mix due to race from the effect of quality of care at facilities that treat a higher percentage of Black patients.

Consequently, it is unknown whether the lower mortality at facilities with greater percentages of Black patients is because Black ESRD patients have lower mortality than non-Black patients, or if it is because such facilities provide better care.

Figure 1 also shows a race-adjusted analysis of facility-level mortality with %Black. The adjusted analysis shows that when mortality at a facility is compared to the mortality that would be expected for the race mix of patients, those facilities treating higher percentages of Black patients have higher mortality, on average. Figure 2 shows that the elevated mortality at such facilities is seen among both Black and non-Black patients at those facilities. The range of disparity in mortality exceeds 10%.

In the ESRD setting, the unadjusted analysis suggests that facilities treating larger percentages of Black patients have lower mortality, but cannot answer the question of how much of that trend is due to lower mortality among black patients. The adjusted analysis, simultaneously accounting for both facility differences and for patient-covariates, suggests very strongly that, in fact, facilities treating a higher % of Black patients tend to have higher mortality, when compared to the mortality that would be expected given their case mix. In the ESRD dialysis setting, mortality analyses that are adjusted for race appear to provide the clearest evaluation of the quality of care that is provided by facilities and these adjusted analyses do not obscure disparities in access to health care, but instead, appear to clarify those disparities.

2b4.3 Testing Results (*Statistical risk model: Provide quantitative assessment of relative contribution of model risk factors; risk model performance metrics including cross-validation discrimination and calibration statistics, calibration curve and risk decile plot, and assessment of adequacy in the context of norms for risk models. Risk stratification: Provide quantitative assessment of relationship of risk factors to the outcome and differences in outcomes among the strata*):

Decile plots showing estimates of the cumulative rates by years of follow up are plotted in Figure 3 (please see the attachment SMR_Risk_Adjustment_Figures_1110.docx). 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 95% for those patients predicted to have the lowest mortality rates (group 1 in black) down to 55% for those predicted to have the lowest rates of survival (group 10 in pink).

The Comorbidity Index is appropriately treated in the SMR model. This is illustrated by comparing a Comorbidity Index decile plot that treats the index as a continuous variable (Figure 4) with a decile plot with the Comorbidity Index = 0 indicator (Figure 6). In Figure 5, we can see a non-linearity clustered at 0 with a significant portion >20%. However, with the indicator there is a reduction of 1050 in the -2LogLikelihood, which is supported by the decile plot (Figure 5).

Similarly, comparing decile plots of log(BMI) without (Figure 6) and with a linear spline (Figure 7) supports modeling log(BMI) using a linear spline with a single knot at 3.5. Furthermore, the model with a linear spline had a reduction of 636 in the -2LogLikelihood compared to the model without the linear spline.

Since age has an interaction with race (black versus non-black) they are plotted separately in two trajectories in the decile plot (Figure 8). This plot shows that the knot at age 14 included in our model works well for both races.

2b4.4 If outcome or resource use measure is not risk adjusted, provide rationale and analyses to justify lack of adjustment: N/A

2b5. Identification of Meaningful Differences in Performance. (*The performance measure scores were appropriately analyzed and discriminated meaningful differences in quality.*)

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2b5.1 Data/Sample (Describe the data or sample including number of measured entities; number of patients; dates of data; if a sample, characteristics of the entities included):

Assessment of the SMR was made using data on hospitalizations among ESRD patients over a four year period of 2006 to 2009.

2b5.2 Analytic Method (Describe methods and rationale to identify statistically significant and practically/meaningfully differences in performance):

We assert statistical and/or clinical significance if a test of the null hypothesis that the SMR is different from 1.0 at the 5% level.

2b5.3 Results (Provide measure performance results/scores, e.g., distribution by quartile, mean, median, SD, etc.; identification of statistically significant and meaningfully differences in performance):

For the data over 2006-2009, 7.9% of facilities had an SMR that was significantly below 1.0, and 10.3% of facilities had an SMR that was significantly above 1.0.

2b6. Comparability of Multiple Data Sources/Methods. (If specified for more than one data source, the various approaches result in comparable scores.)

2b6.1 Data/Sample (Describe the data or sample including number of measured entities; number of patients; dates of data; if a sample, characteristics of the entities included):

N/A

2b6.2 Analytic Method (Describe methods and rationale for testing comparability of scores produced by the different data sources specified in the measure):

N/A

2b6.3 Testing Results (Provide statistical results, e.g., correlation statistics, comparison of rankings; assessment of adequacy in the context of norms for the test conducted):

N/A

2c. Disparities in Care: H M L I NA (If applicable, the measure specifications allow identification of disparities.)

2c.1 If measure is stratified for disparities, provide stratified results (Scores by stratified categories/cohorts): N/A

2c.2 If disparities have been reported/identified (e.g., in 1b), but measure is not specified to detect disparities, please explain:

N/A

2.1-2.3 Supplemental Testing Methodology Information:

Attachment

SMR_Risk_Adjustment_Figures_1110.docx

Steering Committee: Overall, was the criterion, *Scientific Acceptability of Measure Properties*, met?

(Reliability and Validity must be rated moderate or high) Yes No

Provide rationale based on specific subcriteria:

If the Committee votes No, STOP

3. USABILITY

Extent to which intended audiences (e.g., consumers, purchasers, providers, policy makers) can understand the results of the measure and are likely to find them useful for decision making. (evaluation criteria)

C.1 Intended Purpose/ Use (Check all the purposes and/or uses for which the measure is intended): [Public Reporting, Quality Improvement \(Internal to the specific organization\)](#), [Quality Improvement with Benchmarking \(external benchmarking to multiple organizations\)](#)

3.1 Current Use (Check all that apply; for any that are checked, provide the specific program information in the following

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questions): Public Reporting, Public Health/ Disease Surveillance, Regulatory and Accreditation Programs, Quality Improvement with Benchmarking (external benchmarking to multiple organizations), Quality Improvement (Internal to the specific organization)

3a. Usefulness for Public Reporting: H M L I

(The measure is meaningful, understandable and useful for public reporting.)

3a.1. Use in Public Reporting - disclosure of performance results to the public at large (If used in a public reporting program, provide name of program(s), locations, Web page URL(s)). If not publicly reported in a national or community program, state the reason AND plans to achieve public reporting, potential reporting programs or commitments, and timeline, e.g., within 3 years of endorsement: [For Maintenance – If not publicly reported, describe progress made toward achieving disclosure of performance results to the public at large and expected date for public reporting; provide rationale why continued endorsement should be considered.]

Dialysis Facility Compare (DFC) web site (www.medicare.gov).

3a.2. Provide a rationale for why the measure performance results are meaningful, understandable, and useful for public reporting. If usefulness was demonstrated (e.g., focus group, cognitive testing), describe the data, method, and results: The language has been consumer tested. Please see: Trisolini M, Roussel A, Harris S, Bandel K, Salib P, Schatell D, Cell J, Klicko K. Evaluation of the Content of the Dialysis Facility Compare Website: Final Report. Prepared for the Centers for Medicare & Medicaid Services under Contract No. 500-00-0024. Waltham, Massachusetts: RTI International, 2004.

The web site has been tested with focus group(s). Please see: Trisolini M, Zerhusen E, Bandel K, Roussel A, Frederick P, Schatell D, Harris S. Evaluation of the Dialysis Facility Compare Website Tool on Medicare.gov. Dialysis & Transplantation 2006 April: pp 1-8.

3.2 Use for other Accountability Functions (payment, certification, accreditation). If used in a public accountability program, provide name of program(s), locations, Web page URL(s): N/A

3b. Usefulness for Quality Improvement: H M L I

(The measure is meaningful, understandable and useful for quality improvement.)

3b.1. Use in QI. If used in quality improvement program, provide name of program(s), locations, Web page URL(s):

[For Maintenance – If not used for QI, indicate the reasons and describe progress toward using performance results for improvement].

This measure has been in use in the Dialysis Facility Reports (formerly Unit-Specific Reports) since 1995 and on the Dialysis Facility Compare (DFC) web site (www.medicare.gov) since 2001, when the Balanced Budget Act (1997) required a system to measure and report the quality of dialysis services under Medicare.

The Dialysis Facility Reports are used by the dialysis facilities and ESRD Networks for quality improvement, and by ESRD state surveyors for monitoring and surveillance. The Standardized Mortality Ratio (SMR) in particular is used by ESRD state surveyors in conjunction with other standard criteria for prioritizing and selecting facilities to survey.

3b.2. Provide rationale for why the measure performance results are meaningful, understandable, and useful for quality improvement. If usefulness was demonstrated (e.g., QI initiative), describe the data, method and results:

The Standardized Mortality Ratio (SMR) is used by ESRD state surveyors in conjunction with other standard criteria for prioritizing and selecting facilities to survey and has been found to be predictive of citations in the past (ESRD State Outcomes List).

Overall, to what extent was the criterion, Usability, met? H M L I

Provide rationale based on specific subcriteria:

4. FEASIBILITY

Extent to which the required data are readily available, retrievable without undue burden, and can be implemented for performance measurement. (evaluation criteria)

4a. Data Generated as a Byproduct of Care Processes: H M L I

4a.1-2 How are the data elements needed to compute measure scores generated? (Check all that apply).

Data used in the measure are:

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generated by and used by healthcare personnel during the provision of care, e.g., blood pressure, lab value, medical condition, Coded by someone other than person obtaining original information (e.g., DRG, ICD-9 codes on claims), Abstracted from a record by someone other than person obtaining original information (e.g., chart abstraction for quality measure or registry)

4b. Electronic Sources: H M L I

4b.1 Are the data elements needed for the measure as specified available electronically (*Elements that are needed to compute measure scores are in defined, computer-readable fields*): ALL data elements are in a combination of electronic sources

4b.2 If ALL data elements are not from electronic sources, specify a credible, near-term path to electronic capture, OR provide a rationale for using other than electronic sources:

4c. Susceptibility to Inaccuracies, Errors, or Unintended Consequences: H M L I

4c.1 Identify susceptibility to inaccuracies, errors, or unintended consequences of the measurement identified during testing and/or operational use and strategies to prevent, minimize, or detect. If audited, provide results:

There are no potential barriers to retrieving data necessary for the measure, and there are no data availability issues.

4d. Data Collection Strategy/Implementation: H M L I

A.2 Please check if either of the following apply (*regarding proprietary measures*):

4d.1 Describe what you have learned/modified 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 (*e.g., fees for use of proprietary measures*):

Data are derived from an extensive national ESRD patient database, which is largely derived from the CMS Program Medical Management and Information System (PMMIS/REMIS), the Standard Information Management System (SIMS) database maintained by the 18 ESRD Networks, the CMS Annual Facility Survey (Form CMS-2744), Medicare dialysis and hospital payment records, the CMS Medical Evidence Form (Form CMS-2728), transplant data from the Organ Procurement and Transplant Network (OPTN), the Death Notification Form (Form CMS-2746), the Nursing Home Minimum Dataset, and the Social Security Death Master File (SSDMF). The database is comprehensive for Medicare patients. Non-Medicare patients are included in all sources except for the Medicare payment records. SIMS provides tracking by dialysis provider and treatment modality for non-Medicare patients. SIMS and billing data have high agreement (94%) about patient placement. Information on death is obtained from several sources which include PMMIS, the Death Notification Form (Form CMS-2746), and the SSDMF. The Social Security Death Master File SSDMF is used to supplement death information (1% of deaths). Method of combining SSDMF with other sources of death data has been validated for transplant recipients. See: Dickinson DM, Dykstra DM, Levine GN, Li S, Welch JC, Webb RL. Transplant data: sources, collection and research considerations, 2004. Am J Transplant. 2005 Apr; 5(4 Pt 2):850-61.

Overall, to what extent was the criterion, *Feasibility*, met? H M L I

Provide rationale based on specific subcriteria:

OVERALL SUITABILITY FOR ENDORSEMENT

Does the measure meet all the NQF criteria for endorsement? Yes No

Rationale:

If the Committee votes No, STOP.

If the Committee votes Yes, the final recommendation is contingent on comparison to related and competing measures.

5. COMPARISON TO RELATED AND 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 before a final recommendation is made.

5.1 If there are related measures (*either same measure focus or target population*) or competing measures (*both the same measure focus and same target population*), list the NQF # and title of all related and/or competing measures:

5a. Harmonization
5a.1 If this measure has EITHER the same measure focus OR the same target population as NQF-endorsed measure(s) : Are the measure specifications completely harmonized?
5a.2 If the measure specifications are not completely harmonized, identify the differences, rationale, and impact on interpretability and data collection burden:
5b. Competing Measure(s)
5b.1 If this measure has both the same measure focus and the same target population as NQF-endorsed measure(s): Describe why this measure is superior to competing measures (<i>e.g., a more valid or efficient way to measure quality</i>); OR provide a rationale for the additive value of endorsing an additional measure. (<i>Provide analyses when possible</i>):

CONTACT INFORMATION
Co.1 Measure Steward (Intellectual Property Owner): Centers for Medicare & Medicaid Services, 7500 Security Boulevard , Mail Stop S3-01-02, Baltimore, Maryland, 21244-1850
Co.2 Point of Contact: Edward O., Garcia III, MHS, Health Policy Analyst, MMSNQF@hsag.com, 410-786-6738-
Co.3 Measure Developer if different from Measure Steward: Arbor Research/UM-KECC, 340 East Huron St., Suite 300, Ann Arbor, Michigan, 48104
Co.4 Point of Contact: Claudia, Dahlerus, Claudia.Dahlerus@arborresearch.org, 734-665-4108-
Co.5 Submitter: Thomas, Dudley, Thomas.Dudley@cms.hhs.gov, 410-786-1442- , Centers for Medicare & Medicaid Services
Co.6 Additional organizations that sponsored/participated in measure development:
Co.7 Public Contact: ESRD Quality Measures, Help Desk, ESRD_quality_measures@arborresearch.org, 877-665-1680- , Arbor Research Collaborative for Health

ADDITIONAL INFORMATION
Workgroup/Expert Panel involved in measure development Ad.1 Provide a list of sponsoring organizations and workgroup/panel members' names and organizations. Describe the members' role in measure development. A technical expert panel was held in September 2006 to review and update this measure.
Ad.2 If adapted, provide title of original measure, NQF # if endorsed, and measure steward. Briefly describe the reasons for adapting the original measure and any work with the original measure steward:
Measure Developer/Steward Updates and Ongoing Maintenance Ad.3 Year the measure was first released: 1995 Ad.4 Month and Year of most recent revision: 02, 2007 Ad.5 What is your frequency for review/update of this measure? Every 3 years Ad.6 When is the next scheduled review/update for this measure? 06, 2013
Ad.7 Copyright statement:
Ad.8 Disclaimers:
Ad.9 Additional Information/Comments: This form was revised on November 17, 2011. The items revised were De.1, 2b4.2, 2b4.3, and 3.1. The attachment containing risk adjustment figures was also revised.

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Date of Submission (MM/DD/YY): 06/23/2011

Standardized Mortality Ratio: Risk Adjustment Strategy

Figure 1: Comorbidity Index Risk Decile Plot

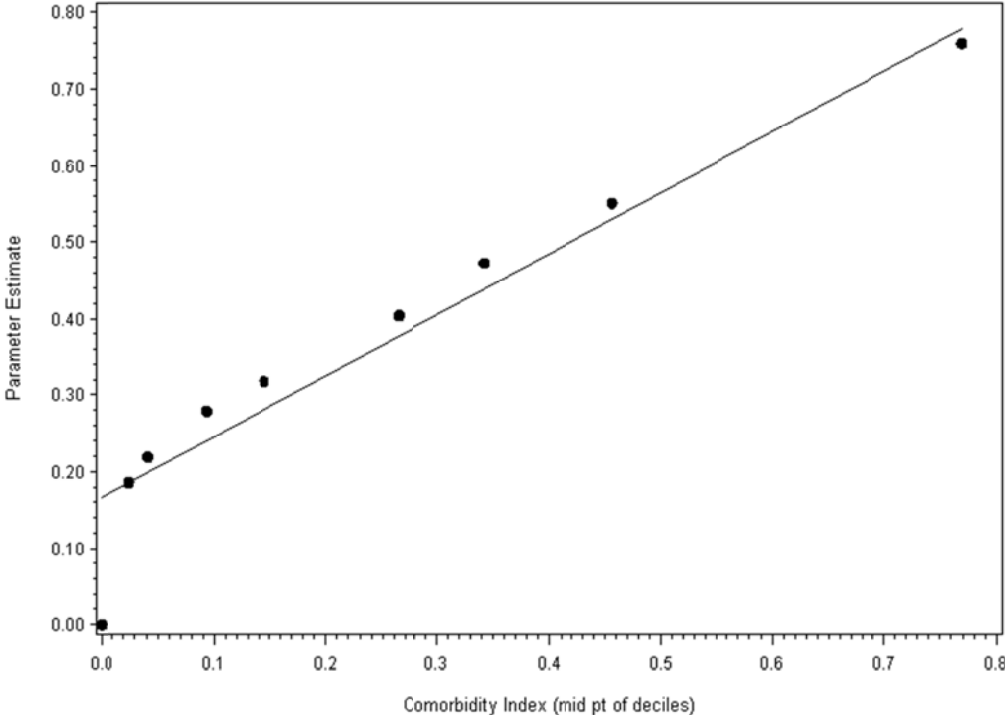


Figure 2: Risk Decile Plot for Comorbidity Index with Comorbidity Index = 0 Indicator

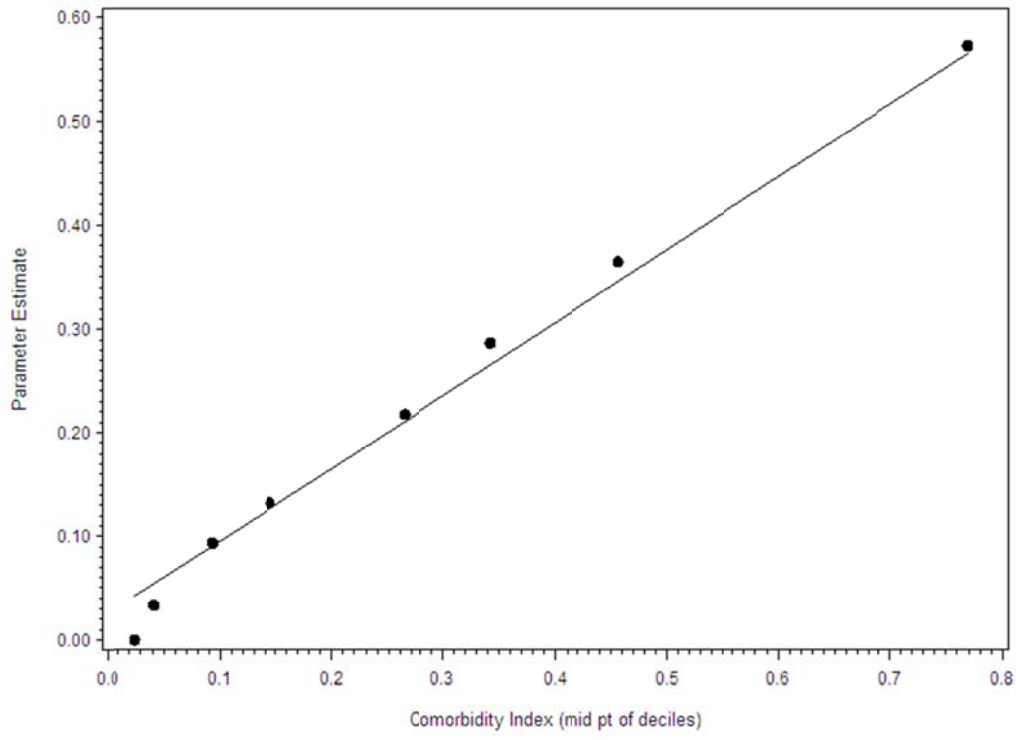


Figure 3: Risk Decile Plot for Log(BMI)

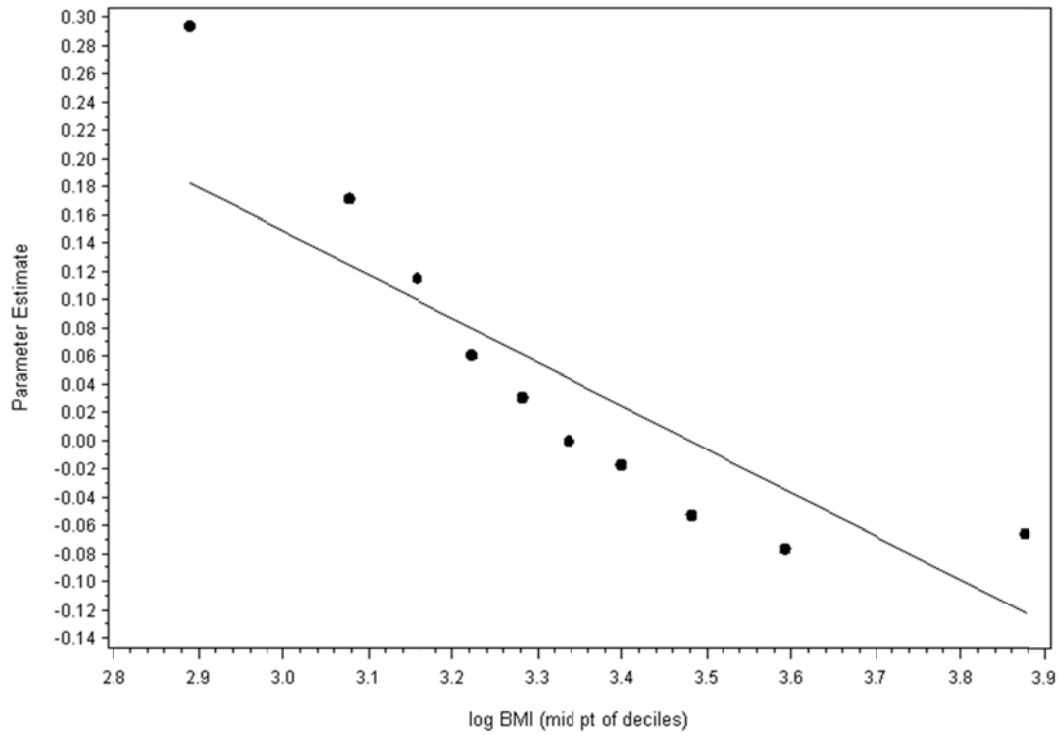


Figure 4: Risk Decile Plot for Log(BMI) with Knot at Log(BMI) = 3.5

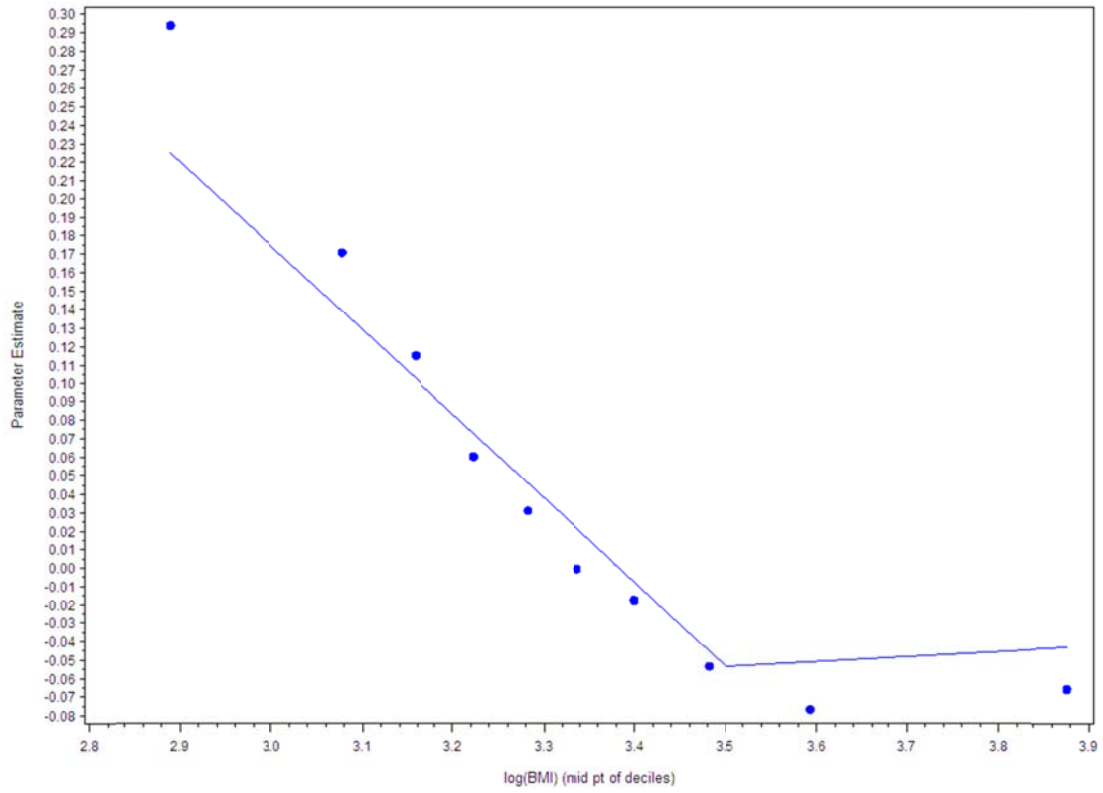


Figure 5: Risk Decile Plot for Age

