MEASURE INFORMATION FORM

Project Title:

Dialysis Facility Compare – Standardized Mortality Ratio

Project Overview:

The Centers for Medicare & Medicaid Services (CMS) has contracted with the University of Michigan Kidney Epidemiology and Cost Center (UM-KECC) to calculate and report quality measures for public reporting on Dialysis Facility Compare.. The contract name is ESRD Quality Measure Development, Maintenance, and Support. The contract number is HHSM-500-2013-13017I.

Date:

Information included is current beginning with the measures reported in the Quarterly Dialysis Facility Compare Preview Period for October 2016 Report.

Measure Name

Dialysis Facility Standardized Mortality Ratio (SMR)

Descriptive Information

Measure Name (Measure Title De.2.)
Dialysis Facility Standardized Mortality Ratio (SMR)

Measure Type De.1.
Outcome

Brief Description of Measure De.3.
The SMR is designed to reflect the number of deaths for the patients at a facility, relative to the number of deaths that would be expected based on overall national rates and the characteristics of the patients at that facility. Specifically, the SMR is calculated as the ratio of two numbers; the numerator ("observed") is the actual number of deaths, excluding deaths due to street drugs and accidents unrelated to treatment, over a specified time period. The denominator ("expected") is the number of deaths that would be expected if patients at that facility died at the national rate for patients with similar characteristics, over the same time period.

If Paired or Grouped De.4.
N/A

Subject/Topic Areas De.5.
Renal: Renal, Renal: End State Renal Disease

Crosscutting Areas De 6.
N/A

Measure Specifications

Measure-specific Web Page S.1.
N/A

If This Is an eMeasure S.2a.
N/A

Data Dictionary, Code Table, or Value Sets S.2b.

Available in attached Excel or csv file

For Endorsement Maintenance S.3.
This form is being used for endorsement maintenance. Minor updates have been made to the model used to calculate the measure. The model now adjusts for each incident comorbidity separately rather than using a comorbidity index. We have also modified the indicators for diabetes by consolidating the individual indicators.

Numerator Statement S.4.
Number of deaths among eligible patients at the facility during the time period.

Time Period for Data S.5.
At least one year.

Numerator Details S.6.
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 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 from the calculations.

Denominator Statement S.7.
Number of deaths that would be expected among eligible dialysis patients at the facility during the time period, given the mortality rate is at the national average and the patient mix at the facility.

Target Population Category S.8.
Populations at Risk : Populations at Risk

Denominator Details S.9.
UM-KECC's treatment history file provides a complete history of the status, location, and dialysis treatment modality of an ESRD patient from the date of the first ESRD service until the patient dies or the data collection cutoff date is reached. For each patient, a new record is created each time he/she changes facility or treatment modality. Each record represents a time period associated with a specific modality and dialysis facility. CROWNWeb is the primary basis for placing patients at dialysis facilities and dialysis claims are used as an additional source. Information regarding first ESRD service date, death and transplant is obtained from additional sources including the CMS Medical Evidence Form (Form CMS-2728), transplant data from the Organ Procurement and Transplant Network (OPTN), the Death Notification Form (Form CMS-2746) and the Social Security Death Master File.

The denominator for SMR for a facility is the total number of expected deaths during all patient-records at the facility. The number of days at risk in each of these patient-records is used to calculate the expected number of deaths for that patient-record.

The denominator is based on expected mortality calculated from a Cox model (Cox, 1972; SAS Institute Inc., 2004; Kalbfleisch and Prentice, 2002; Collett, 1994). The model used is fit in two stages. The stage 1 model is a Cox model stratified by facility and adjusted for patient age, race, ethnicity, sex, diabetes, duration of ESRD, nursing home status, patient comorbidities at incidence, calendar year and body mass index (BMI) at incidence. This model allows the baseline survival probabilities to vary between strata (facilities), and assumes that the regression coefficients are the same across all strata. Stratification by facility at this stage avoids biases in estimating regression coefficients that can occur if the covariate distributions vary substantially across centers. The results of this analysis are estimates of the regression coefficients in the Cox model and these provide an estimate of the relative risk for each patient. This is based on a linear predictor that arises from the Cox model, and is then used as an offset in the stage 2 model, which is unstratified and includes an adjustment for the race-specific age-adjusted state population death rates.

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 during the first 90 days of ESRD.

In order to exclude patients who only received temporary dialysis therapy, we assigned patients to a facility only after they had 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 SIMS 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. When patients are treated at the same facility for two or more separate time periods during a year, the days at risk at the facility is the sum of all time spent at the facility for the year so that a given patient can generate only one patient-record per year at a given facility. For example, consider a who patient spends two periods of 100 days assigned to a facility, but is assigned to a different facility for the 165 days between these two 100-day periods. This patient will give rise to one patient-record of 200 days at risk at the first facility, and a separate patient-record of 165 days at risk at the second facility.

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 death for that facility. Detailed methodology is described in Statistical Risk Model and Variables S.14.

Denominator Exclusions (NQF Includes "Exceptions" in the "Exclusion" Field) S.10.

N/A

Denominator Exclusion Details (NQF Includes "Exceptions" in the "Exclusion" Field) S.11.

N/A

Stratification Details/Variables S.12.

N/A

Risk Adjustment Type S.13.
Statistical risk model

Statistical Risk Model and Variables S.14.
The SMR is based on expected mortality calculated from a Cox model (Cox, 1972; SAS Institute Inc., 2004; Kalbfleisch and Prentice, 2002; Collett, 1994). The model used is fit in two stages. The stage 1 model is a Cox model stratified by facility and adjusted for patient age, race, ethnicity, sex, diabetes as cause of ESRD, duration of ESRD, nursing home status from previous year, patient comorbidities at incidence, calendar year and body mass index (BMI) at incidence. This model allows the baseline survival probabilities to vary between strata (facilities), and assumes that the regression coefficients are the same across all strata. Stratification by facility at this stage avoids biases in estimating regression coefficients that can occur if the covariate distributions vary substantially across centers.

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

- Age: We determine each patient's age for the birth date provided in the SIMS and REMIS databases. 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: We determine each patient's sex from his/her Medical Evidence Form (CMS-2728).
- Race (White, Black, Asian/PI, Native American or other): We determine race from REBUS/PMMIS, the EDB (Enrollment Data Base), and SIMS.
- Ethnicity (Hispanic, non-Hispanic or unknown): We determine ethnicity from his/her CMS-2728.
- Diabetes as cause of ESRD: We determine each patient's primary cause of ESRD from his/her CMS-2728.
- Duration of ESRD: We determine each patient's length of time on dialysis using the first service date from his/her CMS-2728, claims history (all claim types), the SIMS database and the SRTR database and categorize as less than one year, 1-2 years, 2-3 years, or 3+ years as of the period start date.
- Nursing home status in previous year: Using the Nursing Home Minimum Dataset, we determine if a patient was in a nursing home the previous year.
- BMI at incidence: We calculate each patient's BMI as the height and weight provided on his/her CMS 2728. BMI is included as a log-linear term. The logarithm of BMI is included as a piecewise continuous log-linear term with different coefficients based on whether the log of BMI is greater or less than 3.5.
- Comorbidities at incidence: We determine each patient's comorbidities at incidence from his/her CMS-2728 namely, alcohol dependence, atherosclerotic heart disease, cerebrovascular disease, chronic obstructive pulmonary disease, congestive heart failure, diabetes (includes currently on insulin, on oral medications, without medications, and diabetic retinopathy), drug dependence, inability to ambulate, inability to transfer, malignant neoplasm, cancer, other cardiac disease, peripheral vascular disease, and tobacco use (current smoker). Each comorbidity is included as a separate

indicator in the model, having a value of 1 if the patient has that comorbidity, and a value of 0 otherwise.. Another categorical indicator variable is included as a covariate in the stage 1 model to flag records where patients have at least one comorbidities. This variable has a value of 1 if the patient has at least one comorbidities and a value of 0 otherwise.

- Calendar year: 2011-2014
- Missing indicator variables: Categorical indicator variables are included as covariates in the stage I model to account for records with missing values for cause of ESRD, comorbidity at incidence(missing CMS-2728 form), and BMI. These variables have a value of 1 if the patient is missing the corresponding variable and a value of 0 otherwise. BMI is imputed when either missing, or outside the range of [10,70) for adults or [5,70) for children. To impute BMI, we used the average values of the group of patients with similar characteristics (age, race, sex, diabetes) when data for all four of these characteristics were available. If either race or diabetes was also missing, the imputation was based on age and sex only. If either age or sex is missing, the patient is excluded from computations.

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

Using the estimates of the regression coefficients from stage 1, we estimate the relative risk for each patient-record. The predicted value for the patient-record from stage 1 is then used as an offset in the stage 2 model, which is unstratified and includes an adjustment for the race-specific age-adjusted state population death rates.

Detailed Risk Model Specifications S.15.

Using the estimates of the regression coefficients from stage 1, we estimate the relative risk for each patient-record. The predicted value for the patient-record from stage 1 is then used as an offset in the stage 2 model, which is unstratified and includes an adjustment for the race-specific age-adjusted state population death rates.

Age-adjusted population death rates (per 100,000) by state and race are obtained from the U.S. Centers for Disease Control National Center for Health Statistics. The 2014 DFR used age-adjusted death rates for 2008-10 from Table 19 of the publication Health, United States, 2013, available at http://www.cdc.gov/nchs/data/hus/hus13.pdf.

Each patient typically gives rise to several patient-records. Specifically, a new patient record is defined for each calendar year and each time a patient changes facilities. The i^{th} patient record is associated with a risk period t_i, which specifies the number of days that the patient is at risk during that record. Note that each patient record corresponds to a single facility and to a single calendar year.

The Cox model is applied in two stages. Stage 1 yields estimates of the coefficients ($ß_j$) for the 56 covariates that are measured on individual patients (or patient-records). The coefficients measure the within-facility effects for individual risk factors or comorbidities. Using these coefficients, a relative risk or predicted risk is calculated for each patient-record. Stage 2 adjusts for the differences in mortality rate at the state level. The model of this stage uses only one covariate, the log of the population death rate for that patient's race within the state where the patient is being treated. The predicted value for the patient-record from stage 1 is used as an offset in the stage 2 model and the stage 2 analysis is not stratified. The combined predicted values from stages 1 and 2, and the baseline survival curve from stage 2 of the Cox model are then used to calculate the expected number of deaths for a specific patient-record.

Let p denotes the number of patient characteristics in the model and x_{ij} be the specific value of the j^{th} characteristic for the i^{th} patient-record. In stage 1, for patient-record i, we denote the measured characteristics or covariates in a vector form as

$$X_i = (x_{i1}, x_{i2}, \ldots, x_{ip})$$

and use this to define the regression portion of a Cox model in which facilities define the strata. Note that for a categorical characteristic, the x_{ij} value is 1 if the patient falls into the category and 0 otherwise. The output of this model is a set of regression coefficients, $ß_1, ß_2, \ldots, ß_p$ and the corresponding predicted value for the i^{th} patient-record is given by

$$X_i ß = ß_1 x_{i1} + ß_2 x_{i2} + \ldots + ß_p x_{ip}. \qquad (1)$$

In stage 2, the only covariate is x_{i0}, which specifies the logarithm of the state age-adjusted population death rate corresponding to the race of the patient giving rise to patient-record i. The stage 2 model is not stratified, so there is a single baseline survival function assumed. The stage 1 $X_i ß$ from equation (1) is used as an offset in the analysis. The Stage 2 Cox model gives rise to an estimate of the regression coefficient $ß_0$ and of the baseline survival function, $S_0(t)$. After stage 2, the linear prediction is

$$A_i = ß_0 x_{i0} + X_i ß = ß_0 x_{i0} + ß_1 x_{i1} + ß_2 x_{i2} + \ldots + ß_p x_{ip}$$

Suppose that t_i is the end of follow-up time for patient-record i, so that $S_0(t_i)$ is the baseline survival probability at time t_i. The survival probability for this patient-record i at time t_i is:

$$S_i(t_i) = [S_0(t_i)]\exp(A_i) .$$

The expected number of deaths for this patient-record during follow-up time t_i arises from considerations in the Cox model and can be written as

$$-ln(S_i(t_i)) = - exp(A_i) \, ln \, [S_0 \, (t_i)].$$

The expected number of deaths at a given facility can now be computed simply by summing these expected values over the totality of patient-records in that facility. Specifically, the expected value is the sum over the N patient-records at the facility giving

$$Exp = \sum_{i=1}^{N} -ln[S_i(t_i)] = -\sum_{i=1}^{N} exp(A_i) \; ln[S_0(t_i)].$$

Note that, patient-records with 100 days of follow-up, who are otherwise the same, give rise to the same expected mortality even if the 100 day period started at different dates during the year. This approximation is made to simplify the calculations.

Let Obs be the total number of deaths observed at the facility during the total four year follow up period. As stated above, the SMR is the ratio of the total number of deaths observed to the expected number so that

$$SMR = Obs/Exp.$$

Type of Score S.16.
Ratio

Interpretation of Score S.17.
Better quality = lower score

Calculation Algorithm/Measure Logic S.18.
See denominator details and risk adjustment instructions. Also, a flowchart is included in the appendix.

Calculation Algorithm/Measure Logic Diagram URL or Attachment S.19.
Available in attached appendix

Sampling S.20.
N/A

Survey/Patient-Reported Data S.21.
N/A

Missing Data S.22.
Patients with missing data are not excluded from the model. Missing values for cause of ESRD are replaced with the other/unknown category. For the purposes of calculation, either missing, or outside the range of [10,70) for adults or [5,70) for children BMI is replaced with the average

values of the group of patients with similar characteristics (age, race, sex, diabetes as cause of ESRD) when data for all four of these characteristics were available. If either race or diabetes as cause of ESRD was also missing, the imputation was based on age and sex only. In the current SMR model, 30597 (3.70%) patients have imputed BMI. Patients with missing race are included in the "other" race group strata and classified as non-White in the model. Patients with missing ethnicity are classified as "unknown" ethnicity. No patients were missing age, sex, or date of first ESRD treatment. Indicator variables identifying patients with missing values for cause of ESRD, incident comorbidity, and BMI are also included as covariates in the model.

Data Source S.23.
Administrative claims
Electronic Clinical Data: Electronic Clinical Data
CMS Medical Evidence Form (Form CMS-2728)
Transplant data from the Organ Procurement and Transplant Network (OPTN)
Death Notification Form (Form CMS-2746)
Social Security Death Master File.

Data Source or Collection Instrument S.24.
Data for the SMR are derived from an extensive national ESRD patient database, which is largely derived from the CMS Consolidated Renal Operations in a Web-enabled Network (CROWN), which includes Renal Management Information System (REMIS), the CMS Annual Facility Survey (Form CMS-2744), the CMS Medical Evidence Form (Form CMS-2728), and the Death Notification Form (Form CMS-2746); 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.

Data Source or Collection Instrument (Reference) S.25.
No data collection instrument provided

Level of Analysis S.26.
Facility

Care Setting S.27.
Dialysis Facility

Composite Performance Measure S.28.
N/A