

Measure Information Form

General Characteristics

Measure ID:	<i>(Auto-generated, when entered into QMIS by the Measures Manager)</i>
Measure Name:	Facility Patient Survival Classification (based on SMR)
Measure Description:	Risk-adjusted standardized mortality ratio for dialysis facility patients.

CMS contact:

Thomas Dudley, MS, RN

Consumer Care Need

- Living With Illness

Quality Domain

- Effectiveness

Type of Measure

- Outcome

Body System:

Kidney/urinary tract (ESRD)

Variable Characteristics

Measure Care Setting

- Dialysis Facility

Unit of Measurement

- Facility

Consensus Endorsement Status

- Endorsed by NQF

Technical Specifications

Target Population

Age

NA

Gender

- Males and females

Anchor Date

- N/A

Effective Date

- 4/1/08

Effective date basis

- N/A

Payer Source

- Medicare

Measure result reported as

- Positive

Current Alignment with CMS

- N/A

CHI Compliant

- No

Method of Data collection

- Electronic only

Numerator statement

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

Data source

- claim/encounter

Instructions

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.

Other

Codes

CMS Enrollment Data Base and Vital Statistics Record

Numerator Time Window

Four Years

Denominator statement

Number of deaths that would be expected among eligible patients at the facility during the four-year time period, given the patient mix at the facility.

- All dialysis patients who have reached day 90 of ESRD.

Data source

- claim/encounter

Other

Codes

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.

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. 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 from the calculations.

Eligible patients (Time at Risk) at each facility. 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.

Deaths at Each Facility

Only deaths at time of risk described above are included for each facility.

Denominator Time Window

Four Years

Exclusion Criteria

Deaths from street drugs or accidents unrelated to treatment are excluded from the calculation (corresponding time at risk is not excluded).

Data source

- claim/encounter
- MDS
- registry

Exclusion Criteria Time Window
Four Years

History

Measure Status

- Implemented/approved by CMS (01/01/2001)

Measure Developer

- CMS
Contractor: Arbor Research / UM-KECC

Intellectual property status

- Public Domain

Measure Source

- New

CMS Final Approval Date

- 1/1/2001

CMS Implementation Use

- Dialysis Facility Compare

Attachments

The **Measure Justification** is a required attachment

Depending on the measure contract (development/maintenance/reevaluation) and, if the measure is risk adjusted, some of the listed Measures Management System forms may be required:

- Risk Adjustment
- Ad Hoc Measure Reevaluation
- Measure Maintenance Reevaluation
- Comprehensive Measure Reevaluation

Other attachments

Comments:

Measure Justification

Measure ID	(Auto-generated when entered into QMIS)
Measure Name	Facility Patient Survival Classification (based on SMR)
Completed by Initial & Date	CMS Measures Contractor; October 2, 2008
CMS Active Implementation Date	July 1, 2008
Date of Last Review	March 1, 2008

Section I: Importance/Relevance

Epidemiological relevance, Financial relevance, Policy relevance:

Epidemiological: At the end of 2004 there were 335,963 patients being dialyzed of which 104,364 were new (incident) ESRD patients (USRDS 2006). Currently, the ESRD mortality rate is 7-8 times the Medicare population (USRDS, 2006). ESRD mortality in the US was 33% higher than in Europe (Goodkin, 2003), 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 cost for both providers and payers. In 2004, total Medicare costs for the ESRD program were \$20 billion (a 12% increase from 2003), while non-Medicare costs were \$12.4 billion (a 14% increase from 2003) (USRDS 2006).

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 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.

Section 2: Scientific Soundness

Explicit evidence base:

Complete one literature citation for each guideline or study on which the measure is based, stating level of evidence and rating scheme used. A suggested format is below; another format may be used.

Literature citation for clinical guideline

Author Last Name/Organization:
Author First Name:
Title of Chapter or Article:
Title of Book or Journal:
Publication Date:
Journal Volume and Number:
Pages:
Web link:
Level of Evidence and Rating Scheme:

Literature citation for supporting evidence/study

Author Last Name/Organization:
Author First Name:
Title of Chapter or Article:
Title of Book or Journal:
Publication Date:
Journal Volume and Number:
Pages:
Web link:
Level of Evidence and Rating Scheme:

Other aspects of scientific soundness:

Reliability, Validity, and Adequacy of risk adjustment:

Complete one literature citation for each guideline or study used in developing the measure.

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. Level of Evidence and Rating Scheme: A.

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. Level of Evidence and Rating Scheme: B.

Literature Citation for: **Clinical Guideline** **Supporting evidence/study**

1. Wolfe RA, Gaylin DS, Port FK, Held PJ, Wood CL. Using USRDS generated mortality tables to compare local ESRD mortality rates to national rates. *Kidney Int* 1992; 42: 991-96.
2. Wolfe RA. The standardized mortality ratio revisited: improvements, innovations, and limitations. *Am J Kidney Dis.* 1994 Aug;24(2):290-7.
3. 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.
4. Andersen PK, Borgun O, Gill RD, Keiding N. *Statistical Models Based on Counting Processes.* New York: Springer-Verlag; 1993. See pages 334 and 406-407.
5. Collett D. *Modeling Survival Data in Medical Research.* London, England: Chapman and Hall; 1994. See page 153, equation 5.6, and page 151, equation 5.1.
6. Hoem, JM (1987) Statistical analysis of a multiplicative model and its application to the standardization of vital rates: a review. *International Statistical Review* 55, 119-152.
7. Okechukwu CN, Hulbert-Shearon T, Wiggins R, Wolfe RA, Port FK: Lack of correlation between facility -based standardized rates of transplantation and mortality. *American Journal of Kidney Disease*, 40(2): 381-384.
8. 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.

ABSTRACTS:

1. Wolfe RA, Brunton C, Ashby VB, Hulbert-Shearon TE, Port FK, Saran R, Kari J: The Association between Dialysis Practice Patterns, Patient Mortality, and State Surveyor Findings. [Abstract] *J Am Soc Nephrol* 2002; 13: 627A.
2. Wolfe RA, Ashby VB, Hulbert-Shearon TE, Port FK: New dialysis facility mortality statistics SMRs adjust for more patient characteristics. [Abstract] *J Am Soc Nephrol* 2001; 12: A1802.
3. Wolfe RA, Ashby VB, Hulbert-Shearon TE, Roys EC, Port FK: Practice patterns explain variation in mortality among facilities. [Abstract] *J Am Soc Nephrol* 2001; 12: A1801.
4. Wolfe RA, Dhingra RK, Hulbert-Shearon T, Port FK: Association between Urea Reduction Ratios and Standardized Mortality (SMR) and Hospitalization (SHR) Ratios in Dialysis Units. [Abstract] *J Am Soc Nephrol* 2000; 11: 329A .
5. Wolfe RA, Hulbert-Shearon TE, Roys EC, Port, FK: Standardized Mortality (SMR) and Hospitalization (SHR) Ratios by Dialysis Unit Practice Pattern of Anemia Adjusted for Dialysis Dose and Vascular Access Type. [Abstract] *J Am Soc Nephrol* 2000; 11: 247A.
6. Wolfe, RA, Dhingra, RK, Hulbert-Shearon TE, Young EW, Port FK: Association between Vascular Access Type and Standardized Mortality (SMR) and Hospitalization (SHR) Ratios in Dialysis Units. [Abstract] *J Am Soc Nephrol* 2000; 11: 201A .
7. Wolfe RA, Ashby VB, Port FK, Hulbert-Shearon TE, Loos ME, Daugirdas JT, Jones CA, Levin NW. The Association between Regional Death Rates and Standardized Mortality Ratios (SMR) by Health Service Areas (HSA) and Race and Sex Group. [Abstract] *J Am Soc Nephrol* 1998; 9:230A.
8. Ashby VB, Wolfe RA, Loos ME, Port FK: The Effect of Comorbidities on Facility Standardized Mortality Ratios. [Abstract] *J Am Soc Nephrol* 1998; 10.
9. Turenne MN, Loos ME, Port FK, Emmert G, Hulbert-Shearon TE, Wolfe RA, Levine GN, Daugirdas JT, Agodoa LYC, Held PJ. The Impact of Deaths Due to AIDS, Accidents and Street Drugs on Standardized Mortality Ratios (SMRs) by Facility. [Abstract] *J Am Soc Nephrol* 1996; 7 (9): 1467.

EVIDENCE FOR RELIABILITY/VALIDITY TESTING

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). See: Frederick PR, Maxey NL, Clauser SB, & Sugarman JR. *Developing Dialysis*

Facility-Specific Performance Measures for Public Reporting. Health Care Financing Review 2002 Summer; 23(4) pp. 37-50.

In addition, several additional technical meeting have also been held to discuss the technical specifications, reliability and validity of this measure. 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, 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 was convened by Arbor Research Collaborative for Health, contractor to CMS, to review and update this measure.

Reliability:

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 SIMS database maintained by the 18 ESRD Networks, the CMS Annual Facility Survey (Form CMS-2744), Medicare dialysis and hospital payment records, the CMS Medical Evidence Form (Form CMS-2728), transplant data from the Organ Procurement and Transplant Network (OPTN), the Death Notification Form (Form CMS-2746), the Nursing Home Minimum Dataset, and the Social Security Death Master File. The database is comprehensive for Medicare patients. 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 the CMS ESRD Program Medical Management Information System, the Death Notification Form (CMS Form 2746), and the Social Security Death Master File. The Social Security Death Master File (SSDMF) is used to supplement death information (about 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.

Validity:

Hulbert-Shearon TE, Wolfe RA, Held PJ. False Positives (FP) and False Negatives (FN) in Measurement of Standardized Mortality Ratio (SMR). [Abstract] Journal of the American Society of Nephrology 1997; 8: 194A.

Section 3: Usability/Actionability

Provides actionable decision support, Message is clear to recipient, Operational relevance

This measure has been in use in the Dialysis Facility Reports (formerly Unit-Specific Reports) since 2000 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 measure is based on DOQI and KDOQI practice guidelines published in 1997 and 2000, respectively.

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. This adequacy of dialysis measure in particular is used by ESRD state surveyors in conjunction with other standard criteria for prioritizing and selecting facilities to survey. This measure is reported publicly on the DFC web site to assist patients in selecting dialysis facilities.

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.

Section 4: Feasibility

Specifications are well-defined, Reasonable burden of data collection, Minimum distortion

Specifications are well defined. Administration and medical record data is used.

Burden is minimal for current data because it exists. An annual update of comorbidities will create a greater burden.

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 SIMS database maintained by the 18 ESRD Networks, the CMS Annual Facility Survey (Form CMS-2744), Medicare dialysis and hospital payment records, the CMS Medical Evidence Form (Form CMS-2728), transplant data from the Organ Procurement and Transplant Network (OPTN), the Death Notification Form (Form CMS-2746), the Nursing Home Minimum Dataset, and the Social Security Death Master File. The database is comprehensive for Medicare patients. 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 the CMS ESRD Program Medical Management Information System, the Death Notification Form (CMS Form 2746), and the Social Security Death Master File. The Social Security Death Master File (SSDMF) is used to supplement death information (about 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.

Comprehensive Reevaluation

<i>Measure ID</i>	(Auto-generated when entered into QMIS)
Measure Set:	DFC Measures
Measure Name:	Facility Patient Survival Classification (based on SMR)
Measure Description:	Risk-adjusted standardized mortality ratio for dialysis facility patients.
CMS GTL/PO:	Thomas Dudley, MS, RN

Version Changes

Summarize what has changed in this version?

The SMR was endorsed without cut points and levels of statistical significance.

Date of review (NQF approval date(s))
March 2008

I. Summary of Current Performance Data Analysis on Each Measure—(measure data as submitted to NQF).

Attach charts, graphs, or tables, as directed by CMS, that summarize the performance of the measure since it was initially used by CMS (ideally) or at least since it was last evaluated (either at measure inception or previous comprehensive evaluation).

Please see attached: DFC_SMR_supporting graphs.pdf

II. Summary of Analysis of the Comments and Questions Received Going into the TEP and during the NQF comment period:

- A. Importance
- B. Scientific Acceptability
- C. Feasibility
- D. Usability

Some members were concerned with potential misclassifications using the standard method; other members noted that because the conservative measure provided very little differentiation among providers it was less useful. Another concern was the adequacy of the risk adjustment - particularly that new conditions may not be picked up. Some committee members raised the concern that using the standard measure would lead facilities to cherry pick less risky patients; others did not think that was any more of a concern for a mortality measure than other outcome measures. Ultimately, the Steering Committee recommended only the conservative mortality measure for inclusion in the ESRD set. A comment regarding the transfer assignment period was sent to the developer.

III. Environmental scan to identify relevant scientific or other information published since the last time the measure was evaluated.

Document all relevant publications found, with a clear indication of:

- A. The type of information
- B. The level of evidence
- C. The relevant Web address (if the article is accessible via the Web)
- D. A brief synopsis of the information and its relevance to the Comprehensive Reevaluation
 - Example #1 (for new guidelines): “ACC HF guidelines now consider ARBs to be equivalent to ACEIs.”
 - Example #2 (for a study on antibiotics): “Study shows increase in inappropriate use of antibiotics in ER patients since measure was implemented.”

Publication: 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. **Level of evidence:** Evidence includes consistent results from well-designed, well-conducted studies in representative populations that directly assess effects on health (or perception of care) outcomes.) **Web Address:** <http://www.ajkd.org/> **Synopsis:** BACKGROUND: Benefits in terms of reductions in mortality corresponding to improvements in Kidney Disease Outcomes Quality Initiative (K/DOQI) compliance for adequacy of dialysis dose and anemia control have not been documented in the literature. We studied changes in achieving K/DOQI guidelines at the facility level to determine whether those changes are associated with corresponding changes in mortality. METHODS: 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. RESULTS: In 2002, facilities in the lowest quintile of K/DOQI compliance for 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 ($P < 0.0001$). CONCLUSION: Both current practice and changes in practices with regard to achieving anemia and dialysis-dose guidelines are associated significantly with mortality outcomes at the dialysis-facility level.

Publication: 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. **Level of evidence:** Evidence is sufficient to determine effects on health (or perception of care) outcomes, but the strength of the evidence is limited by the number, quality, or consistency of the individual studies, generalizability to routine practice, or indirect nature of the evidence on health outcomes. **Web Address:** <http://www.ajkd.org/> **Synopsis:** BACKGROUND: The Dialysis Outcomes and Practice Patterns Study is well suited to identify case-mix effects, given its extensive data set. The data set was used to examine the influence of case-mix variables on mortality and the extent to which these variables account for differences in mortality across regions, as well as the prevalence and incidence of hepatitis B and hepatitis C. METHODS: Demographic and comorbid disease features were determined for 8,615 patients internationally; mortality was recorded for this cohort, plus replacement patients (total $n = 16,720$), from 1996 to 2002. Mortality was associated with increasing age, nonblack race, coronary artery disease, congestive heart failure, other cardiac disease, diabetes mellitus, peripheral vascular disease, cerebrovascular disease, absence of hypertension, lung disease, cancer, human immunodeficiency virus infection, gastrointestinal bleeding, neurologic disease, psychiatric disease, cellulitis/gangrene, hepatitis C, and smoking. RESULTS: US patients were slightly older than those in Europe or Japan and had the highest prevalence of diabetes, coronary artery disease, congestive heart failure, peripheral vascular disease, and cerebrovascular disease. CONCLUSION: Upon adjusting for case-mix to assess mortality across facilities, it was found that regional differences in mortality (highest in the United States and lowest in Japan) and differences across facilities within nations remain after such corrections. It is likely that practice patterns account for some of this variation. Prevalence of hepatitis B

virus (HBV) across facilities increased as the number of dialyzing patients per facility increased; risk of HBV seroconversion decreased among facilities using protocols for treatment of patients with HBV infection. Greater employment of staff with at least 2 years of formal nursing training was associated with lower prevalence of hepatitis C virus infection and lower seroconversion risk.

List of key publications in refereed journals, book chapters and/ or published reports:

Wolfe RA, Gaylin DS, Port FK, Held PJ, Wood CL. Using USRDS generated mortality tables to compare local ESRD mortality rates to national rates. *Kidney Int* 1992; 42: 991-96.

Wolfe RA. The standardized mortality ratio revisited: improvements, innovations, and limitations. *Am J Kidney Dis.* 1994 Aug;24(2):290-7.

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.

Andersen PK, Borgun O, Gill RD, Keiding N. *Statistical Models Based on Counting Processes.* New York: Springer-Verlag; 1993. See pages 334 and 406-407.

Collett D. *Modeling Survival Data in Medical Research.* London, England: Chapman and Hall; 1994. See page 153, equation 5.6, and page 151, equation 5.1.

Hoem, JM (1987) Statistical analysis of a multiplicative model and its application to the standardization of vital rates: a review. *International Statistical Review* 55, 119-152.

Shih YC, Guo A, Just PM, Mujais S. Impact of initial dialysis modality and modality switches on Medicare expenditures of end-stage renal disease patients. *Kidney Int.* 2005 Jul;68(1):319-29.

Murthy BV, Molony DA, Stack AG. Survival advantage of Hispanic patients initiating dialysis in the United States is modified by race. *J Am Soc Nephrol.* 2005 Mar;16(3):782-90.

Frederick PR, Maxey NL, Clauser SB, Sugarman JR. Developing dialysis facility-specific performance measures for public reporting. 1: *Health Care Financ Rev.* 2002 Summer;23(4):37-50.

Longenecker JC, Coresh J, Klag MJ, Levey AS, Martin AA, Fink NE, Powe NR. Validation of comorbid conditions on the end-stage renal disease medical evidence report: the CHOICE study. *Choices for Healthy Outcomes in Caring for ESRD.* 1: *J Am Soc Nephrol.* 2000 Mar;11(3):520-9.

Lowrie EG, Teng M, Lacson E, Lew N, Lazarus JM, Owen WF: Association between prevalent care process measures and facility specific mortality rates. *Kidney Int.* 2001 (60):1917-1929.

McClellan WM, Soucie JM, Flanders WD: Mortality in end-stage renal disease is associated with facility-tofacility differences in adequacy of hemodialysis. *J Am Soc Nephrol.* 1998 (9):1940-1947.

IV. A technical expert panel was convened: Yes No

If yes, date(s) of the meeting(s):

Clinical-TEP: September 18-19, 2006

Briefly summarize the TEP recommendations here.

Clinical-TEP Recommendations for Changes to Measure

1. The TEP strongly recommended that more categories (5 instead of 3) of survival be considered for display. Since the majority of facilities receive an “as expected” designation under current cutoff rules, additional categories of outcomes should be considered.
2. If only three categories are to be used, the TEP recommended that the categories be reviewed to consider using less stringent criteria for being classified in the extreme categories.
3. The TEP would also like to convert the display to bar graphs instead of check boxes. The bar graphs should be analogous to the anemia management and adequacy measures.
4. The TEP recommended no changes to the current SMR methodology, however, there is room for improvement in better capturing elements for risk adjustment as data becomes available. The current measures are reasonably risk adjusted based upon the constraints of the existing data in the 2728 form. In the future, further analysis should be done with the level of acuity of patients, especially with nursing home patients.

V. If any of the codes used in the technical specifications have changed since the last measure update or comprehensive reevaluation, specify the change(s) with an explanation of its impact on the measure.

N/A

VI. If material¹ changes to the measure have occurred — i.e., wording, data elements, time periods, abstraction instructions, etc. — document them here. If material changes were made to the measure, was the measure tested?

N/A

Yes No

If yes, indicate the results of the testing.

¹ A **material change** is one that changes the intended meaning of the measure or the strength of the measure in terms of measure evaluation criteria. NQF's process for an ad hoc expedited review will be triggered at any point when the measure developer make material changes to the measure construct (including the numerator, denominator, and exclusions) or measure logic. The timing of the ad hoc review will depend on whether there is an accompanying safety concern. If changes to the measure are deemed appropriate:

- Would a change in the measure result in statistical discontinuity from the current measurement baseline?
- Would a change in the measure significantly impact current processes and the burden for data collection, analysis, and reporting?
- Would the proposed change unintentionally result in the modification of a current clinical or administrative practice?

Measure Contractor Recommended Disposition			
Measure contractor recommended disposition of the measure	<input type="checkbox"/> Retain		
			Effective Date of Action
	<input checked="" type="checkbox"/> Revise (as described above)		7/11/2008
	<input type="checkbox"/> Replace		
	<input type="checkbox"/> Rotate		
<input type="checkbox"/> Retire			
Rationale for recommendation			
Effective date basis	<input type="checkbox"/> Discharges	<input type="checkbox"/> Admissions	<input type="checkbox"/> Service Date <input type="checkbox"/> Other:
Recommended by	Name: Date:		

CMS Role	
CMS decision for measure disposition <input type="checkbox"/> Approved as recommended.	<input type="checkbox"/> Retain
	Effective Date of Action
	<input type="checkbox"/> Revise
	<input type="checkbox"/> Replace
<input type="checkbox"/> Rotate	
<input type="checkbox"/> Retire	
Comments about decision	
Approved by	Name: Date:

Risk Adjustment

Measure ID	(Auto-generated when entered into QMIS)
Measure Name	Facility Patient Survival Classification (based on SMR)
Completed by Initial & Date	CMS Measures Contractor; October 2, 2008
CMS Active Implementation Date	July 1, 2008
Date of Last Review	March 1, 2008

Status

- None
 Stratified/group analysis
 Paired/matched data at patient level
 Risk adjusted using publicly or commercially available software
 Risk adjusted using methodology specifically for this measure and condition

Method

- Stratification
 Logistic regression
 Linear regression
 Other

Please give specifics:

Cox model.

DATA ANALYSIS LOGIC AND METHOD

Reference: See Guide to the Dialysis Facility Reports under DFR heading at www.sph.umich.edu/kecc

Time at Risk

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: 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 calculation.

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 (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.

Prior Use of Methodology

- Literature uses essentially the same methodology and variables for the same topic or indicator
- Important modifications are specific to the proposed use

Please give specifics:

Basic Approach

- Empirical
- Theoretical
- Hybrid

Categories for Adjustment

- Genetic
- Demographic
- Comorbidity
- Severity
- Functional Status