

## Measure Justification Form

***Project Title:***

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) develop measures of mortality in ESRD patients. The contract name is ESRD Quality Measure Development, Maintenance, and Support. The contract number is HHSM-500-2013-13017I. Under this contract, UM-KECC held a Technical Expert Panel in September 2015 to provide advice on adjusting the Standardized Mortality Ratio for prevalent comorbidities.

***Date:***

Information included is current on January 29, 2016

**Measure Name** Dialysis Facility Standardized Mortality Ratio (SMR)

**Type of Measure** Outcome

## **Importance**

### **1a—Opportunity for Improvement**

1a.1. This is a Measure of

Health outcome: Mortality

### **1a.2.—Linkage**

1a.2.1 Rationale

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

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

[1]. United States Renal Data System. 2015 USRDS annual data report: Epidemiology of kidney disease in the United States. National Institutes of Health, National Institute of Diabetes and Digestive and Kidney Diseases, Bethesda, MD, 2015.

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

Abstract: Standardized mortality ratios (SMRs) reported by Medicare compare mortality at individual dialysis facilities with the national average, and are currently adjusted for race. However, whether the adjustment for race obscures or clarifies disparities in quality of care for minority groups is unknown. Cox model-based SMRs were computed with and without adjustment for patient race for 5920 facilities in the United States during 2010. The study population included virtually all patients treated with dialysis during this period. Without race adjustment, facilities with higher proportions of black patients had better survival outcomes; facilities with the highest percentage of black patients (top 10%) had overall mortality rates approximately 7% lower than expected. After adjusting for within-facility racial differences, facilities with higher proportions of black patients had poorer survival outcomes among black

and non-black patients; facilities with the highest percentage of black patients (top 10%) had mortality rates approximately 6% worse than expected. In conclusion, accounting for within-facility racial differences in the computation of SMR helps to clarify disparities in quality of health care among patients with ESRD. The adjustment that accommodates within-facility comparisons is key, because it could also clarify relationships between patient characteristics and health care provider outcomes in other settings.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

weight gain and larger weight gain independent of session length are associated with increased mortality.

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

**RESULTS:** Compared with delivered session length  $\geq 240$ , session length  $< 240$  minutes was associated with increased all-cause mortality (adjusted hazard ratio [95% confidence interval], 1.32 [1.03 to 1.69]). Compared with weight gain  $\leq 3$ , weight gain  $> 3$  kg was associated with increased mortality (1.29 [1.01 to 1.65]). The associations were consistent across strata of age, sex, weight, and weight gain and session length. Secondary analyses demonstrated dose-response relationships between both and mortality.

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

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

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

[12]. Block GA, Kilpatrick RD, Lowe KA, Wang W, Danese MD. CKD-mineral and bone disorder and risk of death and cardiovascular hospitalization in patients on hemodialysis. Clin J Am Soc Nephrol. 2013 Dec;8(12):2132-40.

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

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



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

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

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

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

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

**RESULTS:** Patients assigned to low Ca dialysate  $<2.5$  mEq/L were more likely to be exposed to larger serum dialysate Ca gradient and had a greater fall in BP during dialysis treatment. After accounting for covariates and baseline differences, low Ca dialysate  $<2.5$  mEq/L (odds ratio=2.00, 95% confidence interval=1.40-2.90), higher corrected serum Ca (odds ratio=1.10, 95% confidence interval=1.00-1.30), and increasing serum dialysate Ca gradient (odds ratio=1.40, 95% confidence interval=1.10-1.80) were associated with increased risk of sudden cardiac arrest, whereas there were no significant risk associations with QT-prolonging medications.

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

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

BACKGROUND AND OBJECTIVES: Patients receiving dialysis undergo parathyroidectomy to improve laboratory parameters in resistant hyperparathyroidism with the assumption that clinical outcomes will also improve. However, no randomized clinical trial data demonstrate the benefits of parathyroidectomy. This study aimed to evaluate clinical outcomes up to 1 year after parathyroidectomy in a nationwide sample of patients receiving hemodialysis.

DESIGN, SETTING, PARTICIPANTS, & MEASUREMENTS: Using data from the US Renal Data System, this study identified prevalent hemodialysis patients aged  $\geq 18$  years with Medicare as primary payers who underwent parathyroidectomy from 2007 to 2009. Baseline characteristics and comorbid conditions were assessed in the year preceding parathyroidectomy; clinical events were identified in the year preceding and the year after parathyroidectomy. After parathyroidectomy, patients were censored at death, loss of Medicare coverage, kidney transplant, change in dialysis modality, or 365 days. This study estimated cause-specific event rates for both periods and rate ratios comparing event rates in the postparathyroidectomy versus preparathyroidectomy periods.

RESULTS: Of 4435 patients who underwent parathyroidectomy, 2.0% died during the parathyroidectomy hospitalization and the 30 days after discharge. During the 30 days after discharge, 23.8% of patients were rehospitalized; 29.3% of these patients required intensive care. In the year after parathyroidectomy, hospitalizations were higher by 39%, hospital days by 58%, intensive care unit admissions by 69%, and emergency room/observation visits requiring hypocalcemia treatment by 20-fold compared with the preceding year. Cause-specific hospitalizations were higher for acute myocardial infarction (rate ratio, 1.98; 95% confidence interval, 1.60 to 2.46) and dysrhythmia (rate ratio 1.4; 95% confidence interval 1.16 to 1.78); fracture rates did not differ (rate ratio 0.82; 95% confidence interval 0.6 to 1.1).

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Abstract: There should be little doubt regarding the importance of infections in the hemodialysis patient population. For years, the US Renal Data System has reported increasing hospitalization rates for all infectious diagnoses and for bacteremia/sepsis in patients treated with hemodialysis.<sup>1</sup> In 2011, the Centers for Disease Control and Prevention (CDC) reported that although the burden of central line-associated bloodstream infections (BSIs) in hospitalized patients had declined nationally, the estimated burden of central line-associated BSIs in people treated with outpatient hemodialysis was substantial, possibly reaching 37,000 in 2008.<sup>2</sup> Soon after, the US Department of Health and Human Services released their National Action Plan to Prevent Healthcare-Associated Infections (HAIs) for End Stage Renal Disease (ESRD) Facilities.<sup>3</sup> The Action Plan, which was developed by the Federal Steering Committee for the Prevention of HAIs in ESRD Facilities with dialysis community stakeholder input, highlighted BSIs as a top priority for national prevention efforts.

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

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

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

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

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

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

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

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

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

[19]. Dalrymple LS, Mu Y, Nguyen DV, Romano PS, Chertow GM, Grimes B, Kaysen GA, Johansen KL. Risk Factors for Infection-Related Hospitalization in In-Center Hemodialysis. Clin J Am Soc Nephrol. 2015 Dec 7;10(12):2170-80.

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

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

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

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

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

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

improve between 2003 and 2010; although first-year admission rates decreased slightly (from 10.2% to 9.0%), rates for prevalent patients increased from 8.3% to 9.0%.

### **1a.3.—Linkage**

#### 1a.3.1. Source of Systematic Review

N/A

### **1a.4.—Clinical Practice Guideline Recommendation**

#### 1a.4.1. Guideline Citation

N/A

#### 1a.4.2. Specific Guideline

N/A

#### 1a.4.3. Grade

N/A

#### 1a.4.4. Grades and Associated Definitions

N/A

#### 1a.4.5. Methodology Citation

N/A

#### 1a.4.6. Quantity, Quality, and Consistency

N/A

### **1a.5.—United States Preventative Services Task Force Recommendation**

#### 1a.5.1. Recommendation Citation

N/A

#### 1a.5.2. Specific Recommendation

N/A

#### 1a.5.3. Grade

N/A

1a.5.4. Grades and Associated Definitions

N/A

1a.5.5. Methodology Citation

N/A

**1a.6.—Other Systematic Review of the Body of Evidence**

1a.6.1. Review Citation

N/A

1a.6.2. Methodology Citation

N/A

**1a.7.—Findings from Systematic Review of Body of the Evidence Supporting the Measure**

1a.7.1. Specifics Addressed in Evidence Review

N/A

1a.7.2. Grade

N/A

1a.7.3. Grades and Associated Definitions

N/A

1a.7.4. Time Period

N/A

1a.7.5. Number and Type of Study Designs

N/A

1a.7.6. Overall Quality of Evidence

N/A

1a.7.7. Estimates of Benefit

N/A

1a.7.8. Benefits Over Harms



N/A

1a.7.9. Provide for Each New Study

N/A

#### **1a.8.—Other Source of Evidence**

1a.8.1. Process Used

N/A

1a.8.2. Citation

N/A

#### **1b.—Evidence to Support Measure Focus**

1b.1. Rationale

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 (i.e., higher mortality than expected) also promotes quality reviews within a facility.

1b.2. Performance Scores

The Standardized Mortality Ratio varies widely across facilities. For example, for the period 2010 – 2013, the 4 year SMR varied from 0.00 to 3.1. The mean value for 4-year SMR was 1.02 and the standard deviation was 0.28. The data used to calculate these rates is limited to those facilities with at least 3 expected deaths (reflecting how the measure is currently calculated on DFC).

Distribution of the SMR, 2010-2013

2010: Facilities = 5,004, Mean = 1.02, Std Dev = 0.39, Min = 0.00, Max = 3.5

2011: Facilities = 5,155, Mean = 1.02, Std Dev = 0.39, Min = 0.00, Max = 3.4

2012: Facilities = 5,279, Mean = 1.02, Std Dev = 0.39, Min = 0.00, Max = 3.4

2013: Facilities = 5,409, Mean = 1.02, Std Dev = 0.40, Min = 0.00, Max = 4.6

2010-2013: Facilities = 5,935. Mean = 1.02, Std Dev = 0.28, Min = 0.00, Max = 3.1

1b.3. Summary of Data Indicating Opportunity

N/A

#### 1b.4. and 1b.5. Disparities

There is evidence indicating that mortality among black ESRD patients is lower than mortality for white ESRD patients, mortality for Hispanic ESRD patients is lower than mortality for non-Hispanic ESRD patients, and mortality for female ESRD patients is lower than mortality for male ESRD patients (see references below). This might suggest absence of a disparity with respect to black race and ethnicity, and female sex. However, Kalbfleisch et al (2015) demonstrate that when accounting for within facility differences in racial and ethnic composition, SMRs will vary depending on the percent of black patients. Without a race adjustment, identical SMRs for one facility with predominantly white patients and one facility with predominantly black patients, for example, would give the false impression that quality of care at the two facilities was equivalent, when in fact race-adjusted mortality at the facility with more black patients would be lower if performance was identical. This same result holds for ethnicity and sex. As such the SMR is adjusted for all three of these patient characteristics to avoid masking disparities in care across groups.

To examine other sociodemographic disparities we included quintiles of socioeconomic status (defined for each patient as the median zipcode household income). This had little effect on the resulting expected deaths counts from the model.

See the section on risk adjustment for further details on adjustments for race, ethnicity, and sex based on the findings of Kalbfleisch et al (2015).

#### References:

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

Powe, NR. Reverse race and ethnic disparities in survival increase with severity of chronic kidney disease: What does this mean? *Clin J Am Soc Nephrol* 1: 905–906, 2006;

Cowie CC, Port FK, Rust KF, Harris MI: Differences in survival between black and white patients with diabetic end-stage renal disease. *Diabetes Care* 17: 681–687, 1994).

#### **1c.—High Priority**

##### 1c.1. Demonstrated High-Priority Aspect of Health Care

Affects large numbers

Patient/societal consequences of poor quality

Severity of illness

##### 1c.3. Epidemiologic or Resource Use Data

Epidemiological: At the end of 2013 there were 661,648 patients being dialyzed of which 117,162 were new (incident) End Stage Renal Disease (ESRD) patients (USRDS 2015). ESRD mortality in the US was 33% higher than in Europe (Goodkin, 2004), suggesting that this improvement of this outcome is -possible. 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. For example, through effective volume control and fluid weight management' management of mineral and bone disease.

There is substantial evidence on the association between dialysis facility care practices, intermediate outcomes and mortality. For example, these include practices related to adequate dialysis, volume control, and appropriate management of mineral and bone disorder. Port et al, reported that dose of dialysis and BMI were both associated with mortality among hemodialysis patients. [Port 2002.] Flythe and Brunelli (2013) report that high ultrafiltration rates have been shown in several studies to be independently associated with increased risk of mortality. Rivara et al, found that high concentrations of serum calcium and phosphorus were associated with increased mortality (Rivara 2015).

Financial: Inefficient and inappropriate management of all aspects of patient ESRD care carries a high costs for both providers and payers. In 2013, total Medicare costs for the ESRD program were \$30.9 billion (a 1.6% increase from 2012) (USRDS 2015).

Policy: This measure has been in use in the Dialysis Facility Reports since 1995 and on the Dialysis Facility Compare (DFC) web site ([www.medicare.gov](http://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.

#### 1c.4. Citations

United States Renal Data System, 2015 annual data report: An overview of the epidemiology of kidney disease in the United States. National Institutes of Health, National Institute of Diabetes and Digestive and Kidney Diseases, Bethesda, MD, 2015.

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.

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

Rivara M, Ravel V, Kalantar-Zadeh K et al. Uncorrected and Albumin-Corrected Calcium, Phosphorus, and Mortality in Patients Undergoing Maintenance Dialysis. *J Am Soc Nephrol* 26: 2015

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

#### 1c.5. Patient-Reported Outcome Performance Measure (PRO-PM)

N/A

## ***Scientific Acceptability***

### **1.—Data Sample Description**

#### **1.1. What Type of Data was Used for Testing?**

Measure Specified to Use Data From:

administrative claims  
clinical database/registry

Measure Tested with Data From:

administrative claims  
clinical database/registry

#### **1.2. Identify the Specific Dataset**

Data are derived from an extensive national ESRD patient database, which is primarily based on the CMS Consolidated Renal Operations in a Web-enabled Network (CROWN) system. The CROWN data include the Renal Management Information System (REMIS), CROWNWeb facility-reported clinical and administrative data (including CMS-2728 Medical Evidence Form, CMS-2746 Death Notification Form, and CMS-2744 Annual Facility Survey Form data), the historical Standard Information Management System (SIMS) database (formerly maintained by the 18 ESRD Networks until replaced by CROWNWeb in May 2012), the National Vascular Access Improvement Initiative's Fistula First Catheter Last project (in CROWNWeb since May 2012), Medicare dialysis and hospital payment records, transplant data from the Organ Procurement and Transplant Network (OPTN), the Nursing Home Minimum Dataset, the Quality Improvement Evaluation System (QIES) Workbench, which includes data from the Certification and Survey Provider Enhanced Report System (CASPER), the Dialysis Facility Compare (DFC) and the Social Security Death Master File. The database is comprehensive for Medicare patients. Non-Medicare patients are included in all sources except for the Medicare payment records. CROWNWeb provides tracking by dialysis provider and treatment modality for non-Medicare patients. Information on hospitalizations is obtained from Part A Medicare Inpatient Claims Standard Analysis Files (SAFs), and past-year comorbidity is obtained from multiple Part A types (inpatient, home health, hospice, skilled nursing facility claims) and Part B outpatient types of Medicare Claims SAFs.

#### **1.3. What are the Dates of the Data Used in Testing?**

Data from calendar years 2010 through 2013 were used for testing.

#### **1.4. What Levels of Analysis Were Tested?**

Measure Specified to Measure Performance of:

hospital/facility/agency

Measure Tested at Level of:

hospital/facility/agency

1.5. How Many and Which Measured Entities Were Included in the Testing and Analysis?

For each year of the four years from 2010-2013, there were 5,004, 5,155, 5,279, and 5,409 respectively.

1.6. How Many and Which Patients Were Included in the Testing and Analysis?

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

1.7. Sample Differences, if Applicable

N/A

**2a.2—Reliability Testing**

2a2.1. Level of Reliability Testing

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

2a2.2. Method of Reliability Testing

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

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

### 2a2.3. Statistical Results from Reliability Testing

**Table 1: IUR for One-year SMR Overall and by Facility Size, 2010-2013**

Facility Size (Number of patients)	2010		2011		2012		2013	
	IUR	N	IUR	N	IUR	N	IUR	N
All Facilities	0.32	5004	0.26	5155	0.30	5279	0.28	5409
Small (<=45)	0.07	1137	0.06	1205	0.03	1241	0.10	1256
Medium (46–85)	0.19	1924	0.16	1967	0.17	2018	0.17	2132
Large (>=86)	0.48	1943	0.39	1983	0.47	2020	0.42	2022

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

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

### 2a2.4. Interpretation

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

Reliability improved further when four-year data were used. Overall, we found that IUR for the four-year SMR for 2009-2012 is 0.66 which indicates that about sixty percent of the variation in the four-year SMR can be attributed to the between-facility differences (signal) and about forty percent to within-facility variation (noise). This value of IUR indicates a **moderate degree of reliability**. When stratified by facility size, we find that, as expected, larger facilities have greater IUR.

## 2b2—Validity Testing

### 2b2.1. Level of Validity Testing

#### Performance measure score

##### Empirical validity testing

Systematic assessment of face validity of performance measure score as an indicator of quality or resource use (i.e., is an accurate reflection of performance on quality or resource use and can distinguish good from poor performance)

## 2b2.2. Method of Validity Testing

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

The measure is also maintained on face validity. It was reviewed by a TEP in 2006 for potential implementation on DFC. The general consensus was the SMR captured meaningful information on survival that DFC users could use to assess facility quality. In 2015, a TEP was held specifically to consider prevalent comorbidity adjustments for inclusion in the measure. The TEP's recommendations are reflected in the risk adjustment methodology.

## 2b2.3. Statistical Results from Validity Testing

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

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

STrR:  $\rho=0.21$ ,  $p<.0001$

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

Catheter:  $\rho=0.13$ ,  $p<.0001$

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

## 2b2.4. Interpretation

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

## **2b3—Exclusions Analysis**

### 2b3.1. Method of Testing Exclusions

N/A

### 2b3.2. Statistical Results From Testing Exclusions

N/A

### 2b3.3. Interpretation

N/A

## **2b4—Risk Adjustment or Stratification**

### 2b4.1. Method of controlling for differences

Statistical risk model with 232 risk factors (diabetes, sex, age, race, ethnicity, duration of ESRD, BMI at incidence, calendar year, nursing home status, 13 comorbidities at incidence and 210 prevalent comorbidities)

### 2b4.2. Rationale why Risk Adjustment is not Needed

N/A

### 2b4.3. Conceptual, Clinical, and Statistical Methods

The risk adjustment is based on a Cox or relative risk model. The adjustment is made for patient age, sex, race, ethnicity, cause of ESRD, duration of ESRD, nursing home status, BMI at incidence, comorbidities at incidence, prevalent comorbidities, and calendar year. In this model, covariates are taken to act multiplicatively on the death rate and the adjustment model is fitted with facility defining strata so as to provide valid estimates even if the distribution of adjustment variables differs across facilities. Relevant references are Cox (1972) and Kalbfleisch and Prentice (2002). All analyses are done using SAS. The adjustments included in the model are all statistically significant in the model.

In general, adjustment factors were selected based on several considerations. We began with a large set of patient characteristics, including demographics, comorbidities at ESRD incidence, anthropometrics, and other characteristics. Facility characteristics were also considered. These were first evaluated for appropriateness of the adjustment. For instance, it is important not to adjust for factors that reflect the results of treatment. Factors considered appropriate were then investigated with statistical models, including interactions between sets of adjusters, to determine if they were related to mortality. Factors related to the measures were also evaluated for face validity as potential predictors of measures. The SMR is adjusted for state population death rates, no other facility characteristics are employed as adjusters at this time.

More recently, there has been great interest among dialysis care providers and other stakeholders in adjusting for more current (prevalent) comorbidities to reflect the current health status of dialysis patients, and specifically inclusion of conditions associated with mortality. In response CMS contracted with UM-KECC to convene a Technical Expert Panel (TEP) in September 2015 to consider



the addition of prevalent comorbidity risk adjustment. The summary report for the TEP can be found here: <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/MMS/TechnicalExpertPanels.html>. The set of prevalent comorbidities recommended by the TEP for inclusion as risk-adjusters are listed in 2b4.4. The list of comorbidities is reflected in the risk-adjustment methodology and model results for this measure.

**Risk factor selection:** The methods for development of the risk factor models have been published and documented (Wolfe RA et al. 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).

**Race/Ethnicity:** Black dialysis patients have lower death rates than non-black patients (see Kalbfleisch et al, 2015, Powe et al., 2006). Likely as a result of this, facilities with a large proportion of black patients tend to have lower mortality rates than facilities with a lower proportion of black patients when no adjustment is made for race (Figure 1 below). When race is included as an adjuster in the analysis, it is observed that the SMR of facilities with higher proportions of black patients tend to have somewhat higher standardized mortality ratios compared to the unadjusted SMR. There is a possible inequality in care that is hidden by the unadjusted analysis as the unadjusted analysis suggests that facilities treating larger percentages of black patients would have lower mortality.

**Sex:** We adjust for sex in the mortality model because females in the general population have lower mortality rates (CDC National Vital Statistics Reports, Vol. 61, No. 6, October 10, 2012, Table A) than males. This adjustment allows for a fair comparison between dialysis facilities with patient populations that have a different mix of males and females.

**SES:** We assessed sensitivity of SMR with SES included in the model. SMR was adjusted for quintiles of income (defined for each patient's zipcode as the median household income). In this analysis results show that this measure of income did not appear to impact SMRs (Figure 3). We therefore have not included this as an adjustment at this time. We are currently examining other measures of SES and SDS to assess impact on expected mortality and whether it would be appropriate to adjust for these factors. This work is informed by the SDS/SES trial being conducted by NQF. In addition, the forthcoming ASPE [Assistant Secretary for Planning and Evaluation] report will inform future assessment of SES and appropriateness of risk adjusting for factors such as income.

#### References:

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

Powe, NR. Reverse race and ethnic disparities in survival increase with severity of chronic kidney disease: What does this mean? *Clin J Am Soc Nephrol* 1: 905–906, 2006; Cowie CC, Port FK, Rust KF, Harris MI: Differences in survival between black and white patients with diabetic end-stage renal disease. *Diabetes Care* 17: 681–687, 1994

## 2b4.4. Statistical Results

### Model Coefficients

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

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

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

Covariate	Coefficient	p-value
2011	0.10334	<.0001
2012	0.00509	0.3735
2013	Reference	-
<b>Ethnicity</b>		
Hispanic	-0.31125	<.0001
Non-Hispanic ethnicity	Reference	
Unknown ethnicity	0.09259	0.0082
<b>Ethnicity X race: nonwhite interaction</b>		
Hispanic ethnicity	0.30208	<.0001
Unknown ethnicity	0.12773	0.0004
<b>Race X diabetes as cause of ESRD interaction</b>		
Asian/PI	0.04491	0.0405
Black	-0.08505	<.0001
Native American	-0.00639	0.8865
Other	0.10269	0.0266
<b>Time with ESRD X diabetes as cause of ESRD interaction</b>		
< 1 year	-0.20115	<.0001
1 to 2 years	-0.11321	<.0001
2 to 3 years	-0.04516	0.0004
3+ years	Reference	-
<b>Time on ESRD: &lt; 1 year X race interaction</b>		
Asian/PI	-0.13672	<.0001
Black	0.03974	0.0003
Native American	-0.10883	0.0344
Other	0.26902	<.0001
<b>Time on ESRD: &lt; 1 year X sex: female interaction</b>		
	0.00915	0.3193
<b>Sex: female X cause of ESRD: diabetes interaction</b>		
	-0.00839	0.3009
<b>Race: black X sex: female interaction</b>		
	0.06686	<.0001

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

ICD-9 Description	ICD-9 Code	Coefficient	P-value
Protein-cal malnutr NOS	2639	0.19068	<.0001
Aut neurophy in oth dis	3371	0.02175	0.1983
Epilep NOS w/o intr epil	34590	0.10419	<.0001
Cerebral edema	3485	0.21974	<.0001
Subendo infarct, initial	41071	0.28073	<.0001
AMI NEC, unspecified	41080	-0.00835	0.8738
AMI NOS, unspecified	41090	0.04091	0.0037
Intermed coronary synd	4111	0.05768	<.0001
Ac ischemic hrt dis NEC	41189	0.07088	0.0013
Angina pectoris NEC/NOS	4139	0.00621	0.5314
Cardiomyopath in oth dis	4258	0.04292	0.0329
Atriovent block complete	4260	0.15129	<.0001
Parox ventric tachycard	4271	0.18283	<.0001
Parox tachycardia NOS	4272	0.07202	0.0747
Atrial fibrillation	42731	0.24876	<.0001
Atrial flutter	42732	0.06245	<.0001
Sinoatrial node dysfunct	42781	-0.04157	<.0001
Subdural hemorrhage	4321	0.13039	<.0001
Stricture of artery	4471	-0.02833	0.0635
Paralytic ileus	5601	-0.01047	0.5007
Convulsions NEC	78039	0.09323	<.0001
Gangrene	7854	0.17237	<.0001
Cachexia	7994	0.33328	<.0001
Candidal esophagitis	11284	0.21728	<.0001
Sarcoidosis	135	0.0498	0.1881
Malignant neopl rectum	1541	0.30273	<.0001
Mal neo liver, primary	1550	0.36764	<.0001
Mal neo upper lobe lung	1623	0.27901	<.0001
Mal neo bronch/lung NOS	1629	0.41213	<.0001
Malign neopl prostate	185	-0.06496	<.0001
Malig neo bladder NOS	1889	0.19631	<.0001
Malig neopl kidney	1890	-0.04592	0.0198
Malign neopl thyroid	193	-0.24613	<.0001
Secondary malig neo lung	1970	0.5234	<.0001
Second malig neo liver	1977	0.90921	<.0001
Secondary malig neo bone	1985	0.71735	<.0001
Malignant neoplasm NOS	1991	0.35314	<.0001
Oth lymph unsp xtrndlg org	20280	0.20078	<.0001

ICD-9 Description	ICD-9 Code	Coefficient	P-value
Mult mye w/o achv rmson	20300	0.41084	<.0001
Ch lym leuk wo achv rmsn	20410	0.37957	<.0001
Essntial thrombocythemia	23871	0.12789	0.0003
Low grde myelody syn les	23872	0.15381	0.0017
Myelodysplastic synd NOS	23875	0.20555	<.0001
DMII wo cmp nt st uncntr	25000	0.0721	<.0001
DMII wo cmp uncntrld	25002	-0.01161	0.0705
DMII keto nt st uncntrld	25010	0.0982	0.0001
DMII ketoacd uncontrold	25012	0.14458	<.0001
DMI ketoacd uncontrold	25013	0.28449	<.0001
DMII hprosmir uncontrold	25022	0.04571	0.2251
DMII renl nt st uncntrld	25040	0.03375	<.0001
DMI renl nt st uncntrld	25041	0.07679	<.0001
DMII ophth nt st uncntrl	25050	0.00575	0.482
DMI ophth uncntrld	25053	0.0629	0.0443
DMII neuro nt st uncntrl	25060	-0.00885	0.2742
DMI neuro nt st uncntrld	25061	0.03226	0.0203
DMII neuro uncntrld	25062	-0.004	0.7193
DMI neuro uncntrld	25063	0.05321	0.037
DMII circ nt st uncntrld	25070	-0.01444	0.0857
DMI circ nt st uncntrld	25071	-0.02272	0.1652
DMII circ uncntrld	25072	0.00435	0.7765
DMII oth nt st uncntrld	25080	0.12132	<.0001
DMI oth nt st uncntrld	25081	0.09973	<.0001
DMII oth uncntrld	25082	0.05006	0.0001
DMI oth uncntrld	25083	0.14618	<.0001
Glucocorticoid deficient	25541	0.31984	<.0001
Oth severe malnutrition	262	0.17484	<.0001
Dis urea cycle metabol	2706	-0.01549	0.7273
Amyloidosis NEC	27739	0.32816	<.0001
Metabolism disorder NEC	27789	0.13233	0.0078
Morbid obesity	27801	0.00932	0.3779
Obesity hypovent synd	27803	-0.02953	0.3107
Sickle cell disease NOS	28260	0.61472	<.0001
Antin chemo indcd pancyt	28411	0.39212	<.0001
Other pancytopenia	28419	0.17159	<.0001
Neutropenia NOS	28800	0.19529	<.0001
Drug induced neutropenia	28803	0.29116	<.0001
Prim hypercoagulable st	28981	0.15977	<.0001
Senile dementia uncomp	2900	0.07334	<.0001
Senile delusion	29020	0.1114	0.0105
Vascular dementia,uncomp	29040	0.10829	<.0001

ICD-9 Description	ICD-9 Code	Coefficient	P-value
Drug withdrawal	2920	0.13901	0.0014
Dementia w/o behav dist	29410	0.10461	<.0001
Dementia w behavior dist	29411	0.12167	<.0001
Demn NOS w/o behv dstrb	29420	0.15134	<.0001
Mental disor NEC oth dis	2948	0.16473	<.0001
Schizophrenia NOS-unspec	29590	0.16904	<.0001
Depress psychosis-unspec	29620	0.08783	<.0001
Recurr depr psychos-unsp	29630	0.04595	0.0459
Recur depr psych-severe	29633	0.04953	0.0214
Bipolar disorder NOS	29680	0.03951	0.0718
Bipolar disorder NEC	29689	0.0765	0.1406
Episodic mood disord NOS	29690	-0.0061	0.8254
Alcoh dep NEC/NOS-unspec	30390	0.02262	0.4481
Alcoh dep NEC/NOS-remiss	30393	-0.0592	0.1194
Opioid dependence-unspec	30400	0.23963	<.0001
Opioid dependence-contin	30401	0.10216	0.0083
Drug depend NOS-unspec	30490	0.09283	0.0412
Cereb degeneration NOS	3319	0.10725	<.0001
Grand mal status	3453	-0.00454	0.8984
Psymotr epil w/o int epi	34540	-0.05696	0.1739
Anoxic brain damage	3481	0.2873	<.0001
Idio periph neurpthy NOS	3569	0.03128	0.0003
Neuropathy in diabetes	3572	0.0258	0.0042
Critical illness myopathy	35981	-0.10948	0.0009
Prolif diab retinopathy	36202	-0.056	<.0001
Mod nonprolf db retinoph	36205	-0.10539	0.0017
Diabetic macular edema	36207	-0.16216	<.0001
Hyp ht dis NOS w ht fail	40291	-0.01224	0.5579
Pulm embol/infarct NEC	41519	0.02084	0.2221
Prim pulm hypertension	4160	0.05884	0.0002
Chr pulmon heart dis NEC	4168	0.1898	<.0001
Prim cardiomyopathy NEC	4254	0.23084	<.0001
Crbl emblsm w infrct	43411	0.18777	<.0001
Crbl art ocl NOS w infrc	43491	0.12749	<.0001
Aortic atherosclerosis	4400	0.03595	0.0233
Athscl extrm ntv art NOS	44020	0.02718	0.0013
Ath ext ntv at w claudct	44021	0.02956	0.0173
Ath ext ntv at w rst pn	44022	0.0837	<.0001
Ath ext ntv art ulcrtion	44023	0.05416	<.0001
Dsct of thoracic aorta	44101	0.11966	0.0452
Lower extremity aneurysm	4423	0.02375	0.4642
Periph vascular dis NEC	44389	0.02878	0.0596

ICD-9 Description	ICD-9 Code	Coefficient	P-value
Periph vascular dis NOS	4439	0.16444	<.0001
Deep phlebitis-leg NEC	45119	-0.04641	0.1151
Oth inf vena cava thromb	4532	0.30687	<.0001
Ac DVT/emb prox low ext	45341	0.08701	<.0001
Ch DVT/embl low ext NOS	45350	0.05663	0.1025
Ch DVT/embl prox low ext	45351	0.03822	0.3528
Ch emblsm subclav veins	45375	0.16767	<.0001
Ac DVT/embl up ext	45382	0.07744	0.0026
Ac emblsm axillary veins	45384	0.07944	0.049
Ac embl internl jug vein	45386	0.08068	0.0006
Ac embl thorac vein NEC	45387	0.07384	0.0288
Esoph varice oth dis NOS	45621	0.18859	<.0001
Obs chr bronc w(ac) exac	49121	0.13193	<.0001
Obs chr bronc w ac bronc	49122	-0.0088	0.5824
Emphysema NEC	4928	0.07809	<.0001
Chronic obst asthma NOS	49320	0.01834	0.1388
Ch obst asth w (ac) exac	49322	0.01286	0.4885
Bronchiectas w/o ac exac	4940	0.03515	0.3221
Chr airway obstruct NEC	496	0.16266	<.0001
Food/vomit pneumonitis	5070	0.1607	<.0001
Postinflam pulm fibrosis	515	0.15118	<.0001
Lung involv in oth dis	5178	0.15956	0.0088
Ac resp flr fol trma/srg	51851	0.02845	0.355
Ot pul insuf fol trm/srg	51852	-0.06297	0.3178
Other pulmonary insuff	51882	0.09857	<.0001
Chronic respiratory fail	51883	0.11434	<.0001
Acute & chronc resp fail	51884	0.12628	<.0001
Gastrostomy comp - mech	53642	0.15365	<.0001
Regional enteritis NOS	5559	0.12126	0.0002
Ulceratve colitis unspcf	5569	0.02044	0.5561
Chr vasc insuff intest	5571	0.13302	<.0001
Fecal impaction	56032	0.04821	0.1281
Intestinal obstruct NOS	5609	0.08494	<.0001
Alcohol cirrhosis liver	5712	0.15572	<.0001
Cirrhosis of liver NOS	5715	0.41697	<.0001
Hepatic encephalopathy	5722	0.31225	<.0001
Portal hypertension	5723	0.22903	<.0001
Oth sequela, chr liv dis	5728	0.2376	<.0001
Chronic pancreatitis	5771	0.17966	<.0001
Pressure ulcer, low back	70703	0.22465	<.0001
Pressure ulcer, hip	70704	0.24053	<.0001
Pressure ulcer, buttock	70705	0.09838	<.0001

ICD-9 Description	ICD-9 Code	Coefficient	P-value
Ulcer of lower limb NOS	70710	0.09412	<.0001
Ulcer other part of foot	70715	0.08756	<.0001
Ulcer oth part low limb	70719	0.16587	<.0001
Chronic skin ulcer NEC	7078	0.14188	<.0001
Syst lupus erythematosus	7100	0.19554	<.0001
Systemic sclerosis	7101	0.39484	<.0001
Pyogen arthritis-unspec	71100	-0.04327	0.3753
Pyogen arthritis-l/leg	71106	0.02859	0.4542
Rheumatoid arthritis	7140	0.0896	<.0001
Inflamm polyarthrop NOS	7149	-0.02268	0.6699
Sacroiliitis NEC	7202	0.04558	0.2878
Ac osteomyelitis-unspec	73000	-0.04987	0.131
Ac osteomyelitis-ankle	73007	-0.08917	<.0001
Ac osteomyelitis NEC	73008	-0.03235	0.307
Osteomyelitis NOS-hand	73024	0.24478	<.0001
Osteomyelitis NOS-ankle	73027	-0.12149	<.0001
Path fx vertebrae	73313	0.22531	<.0001
Aseptic necrosis femur	73342	0.10754	0.0188
Asept necrosis bone NEC	73349	0.15539	0.006
Coma	78001	0.21242	<.0001
Fracture of pubis-closed	8082	0.11422	0.0001
Pelvic fracture NOS-clos	8088	0.05103	0.1367
Fx femur intrcaps NEC-cl	82009	-0.00952	0.7647
Fx neck of femur NOS-cl	8208	0.04397	0.0051
Fx femur NOS-closed	82100	-0.02136	0.4055
Amput below knee, unilat	8970	-0.09002	<.0001
Amputat bk, unilat-compl	8971	-0.01234	0.7926
Amput above knee, unilat	8972	-0.11732	<.0001
Amputat leg, unilat NOS	8974	-0.08497	0.064
React-indwell urin cath	99664	0.05432	0.0555
Compl heart transplant	99683	0.09947	0.1582
Asymp hiv infectn status	V08	0.46221	<.0001
Heart transplant status	V421	0.19932	0.0002
Liver transplant status	V427	0.03733	0.2656
Trnspl status-pancreas	V4283	0.1358	0.0026
Gastrostomy status	V441	0.02576	0.2534
Ileostomy status	V442	-0.07135	0.0349
Colostomy status	V443	0.01882	0.4186
Urinostomy status NEC	V446	0.27221	<.0001
Respirator depend status	V4611	0.08244	<.0001
Status amput othr toe(s)	V4972	-0.02421	0.1067
Status amput below knee	V4975	0.14259	<.0001

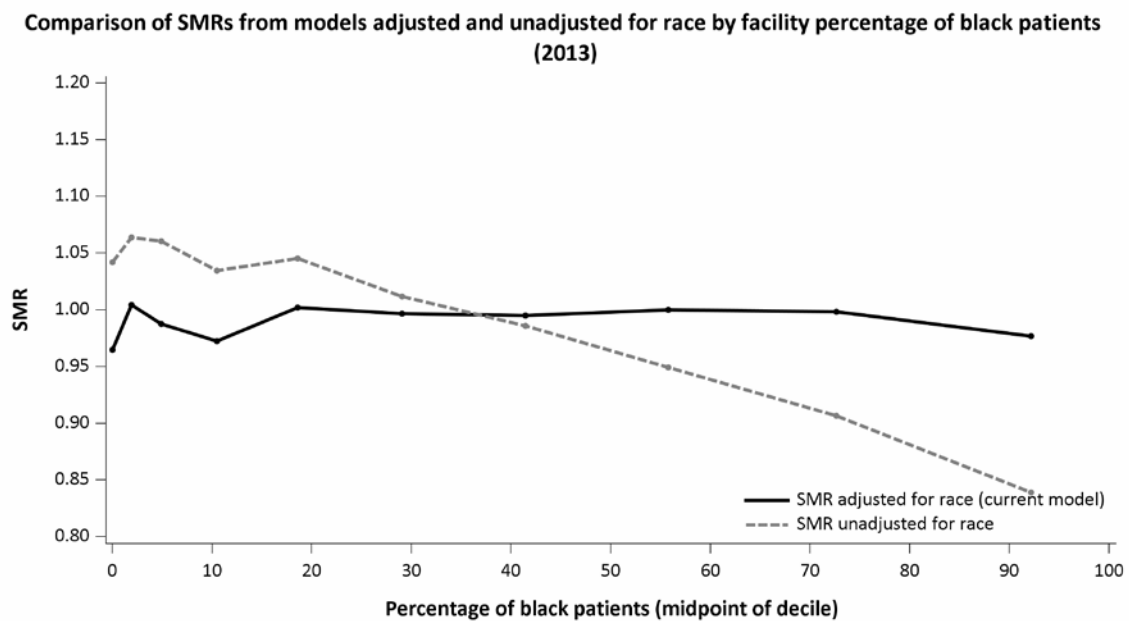


ICD-9 Description	ICD-9 Code	Coefficient	P-value
Status amput above knee	V4976	0.09281	<.0001
Atten to gastrostomy	V551	-0.05311	0.0197
Long-term use of insulin	V5867	0.0585	<.0001
BMI 40.0-44.9, adult	V8541	-0.03968	0.0375
	miss_comorbid	0.53332	<.0001

### Race

The adjusted/unadjusted analysis comparison in Figure 1 helps to address the question as to how much of the difference is due to the fact that black patients have somewhat lower mortality, and gives a better indication of the true facility effects.

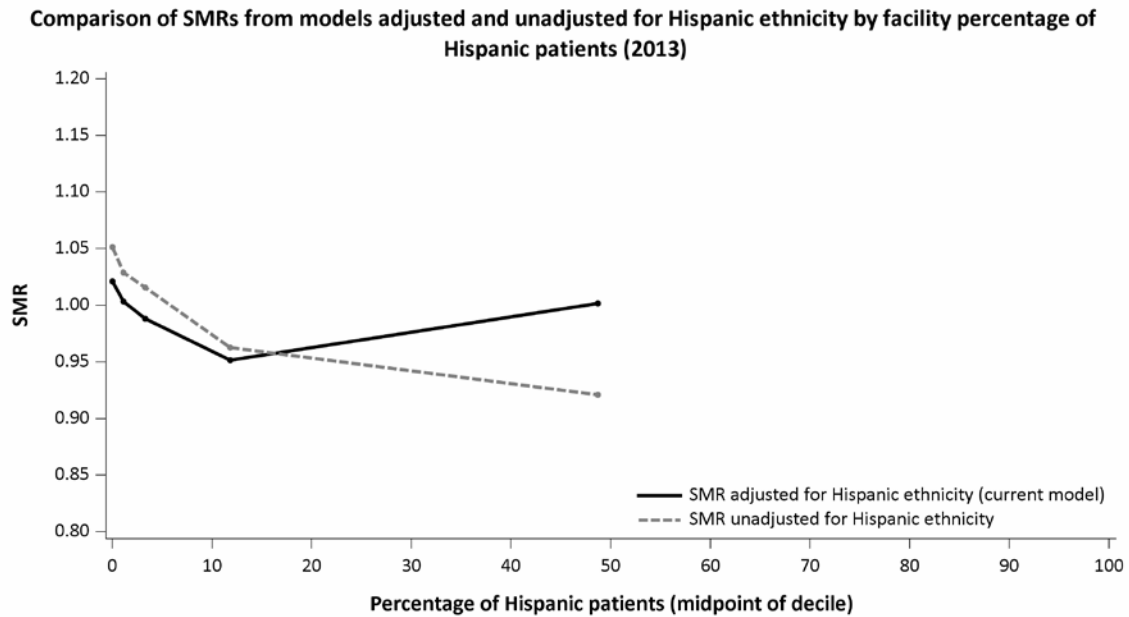
**Figure 1.** Comparison of SMRs adjusted and not adjusted for race by facility percentage of black patients (deciles), 2013



### Ethnicity

We also conducted similar analyses focusing on Hispanic ethnicity (Figure 2). The adjusted/unadjusted analysis comparison helps address the question as to how much of the difference is due to Hispanic patients that have somewhat lower mortality. The comparison provides a better indication of the true facility effects.

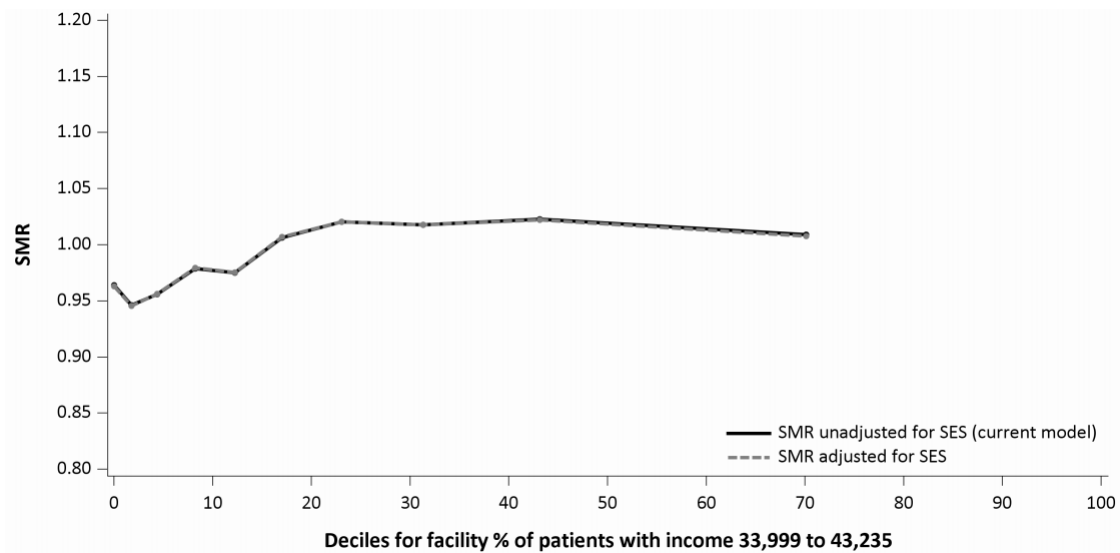
**Figure 2.** SMRs adjusted and not adjusted for ethnicity



### Socioeconomic status

Figure 3 examining our measure of SES indicates that there is little difference in mortality rates between models with (dashed line) and without (solid line) the adjustment for SES.

**Figure 3.** Comparison of SMRs adjusted and not adjusted for SES by facility percentage of patients with household income between \$33,999 to \$43,235(deciles), 2013



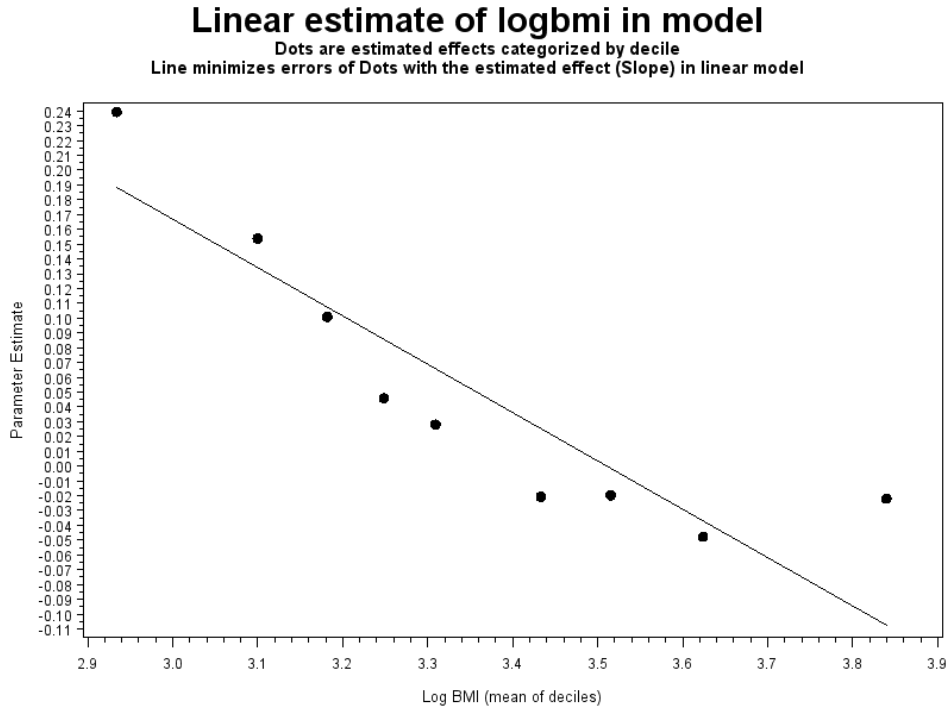
\*The adjusted model included quintiles for SES. SES was defined for each patient as the median zip code household income. Patients without a zip code were assigned the median income in the state.

\*\*Income data source: ACS 2007 to 2011 (5-Year Estimates)(SE), ACS 2007 -- 2011 (5-Year Estimates), Social Explorer, U.S. Census Bureau;

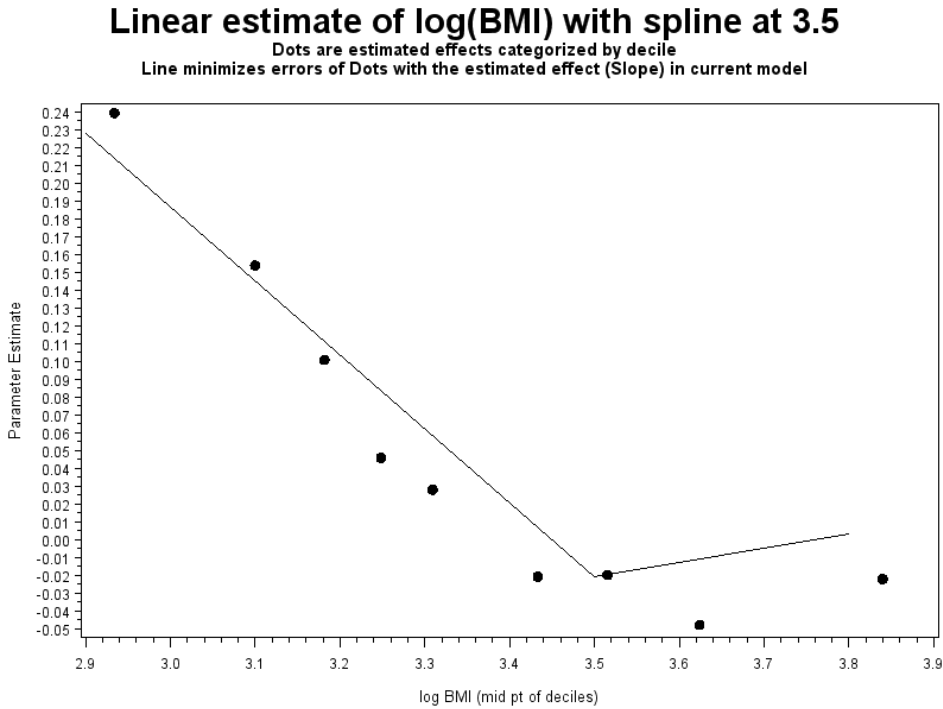
### BMI

Similarly, comparing decile plots of log(BMI) without (Figure 4) and with a linear spline (Figure 5) 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 1673.5 in the -2 log likelihood compared to the model without the linear spline.

**Figure 4.** Risk decile plot for log(BMI)



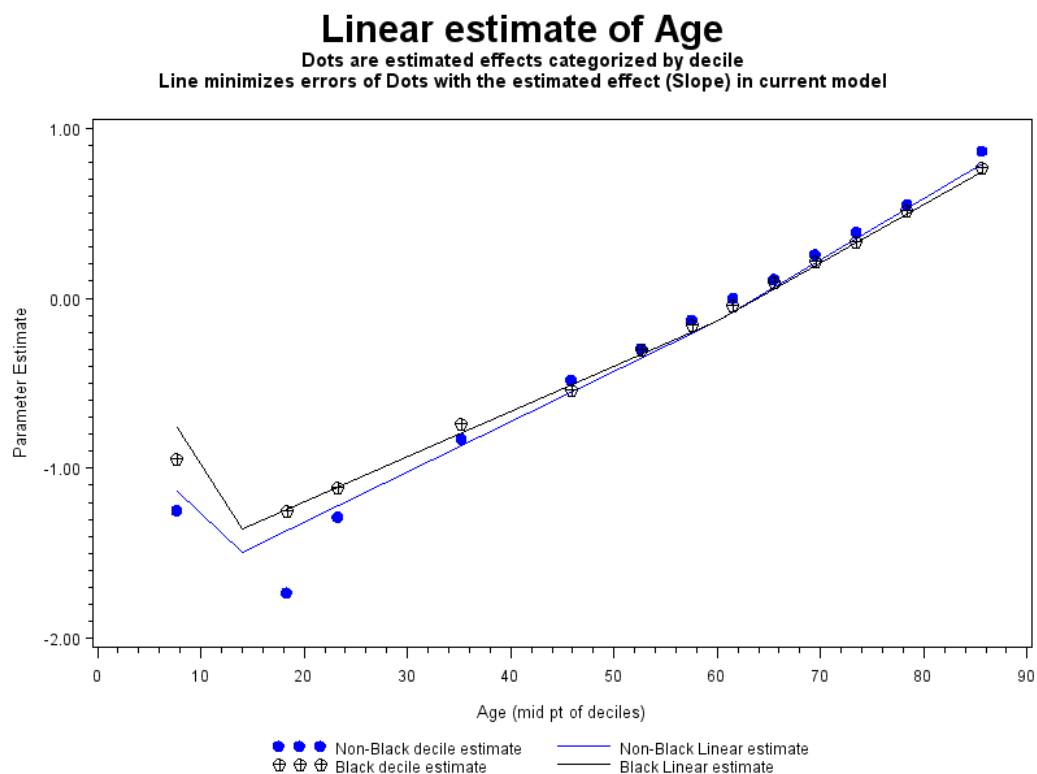
**Figure 5.** Risk decile plot for log(BMI) with knot at log(BMI)=3.5



### Age

Since age has an interaction with race (black: black line versus non-black: blue line), they are plotted separately in two trajectories in the decile plot (Figure 6). This plot shows that the knot at age 14 included in our model works well for both races.

**Figure 6.** Age decile plot



#### 2b4.5. Method Used to Develop the Statistical Model or Stratification Approach

If stratified, skip to 2b4.9

See 2b4.3.

#### 2b4.6. Statistical Risk Model Discrimination Statistics (e.g., c-statistic, $R^2$ )

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

#### 2b4.7. Statistical Risk Model Calibration Statistics (e.g., Hosmer-Lemeshow statistic)

N/A

#### 2b4.8. Statistical Risk Model Calibration—Risk decile plots or calibration curves

See Figure 7 in 2b4.10.

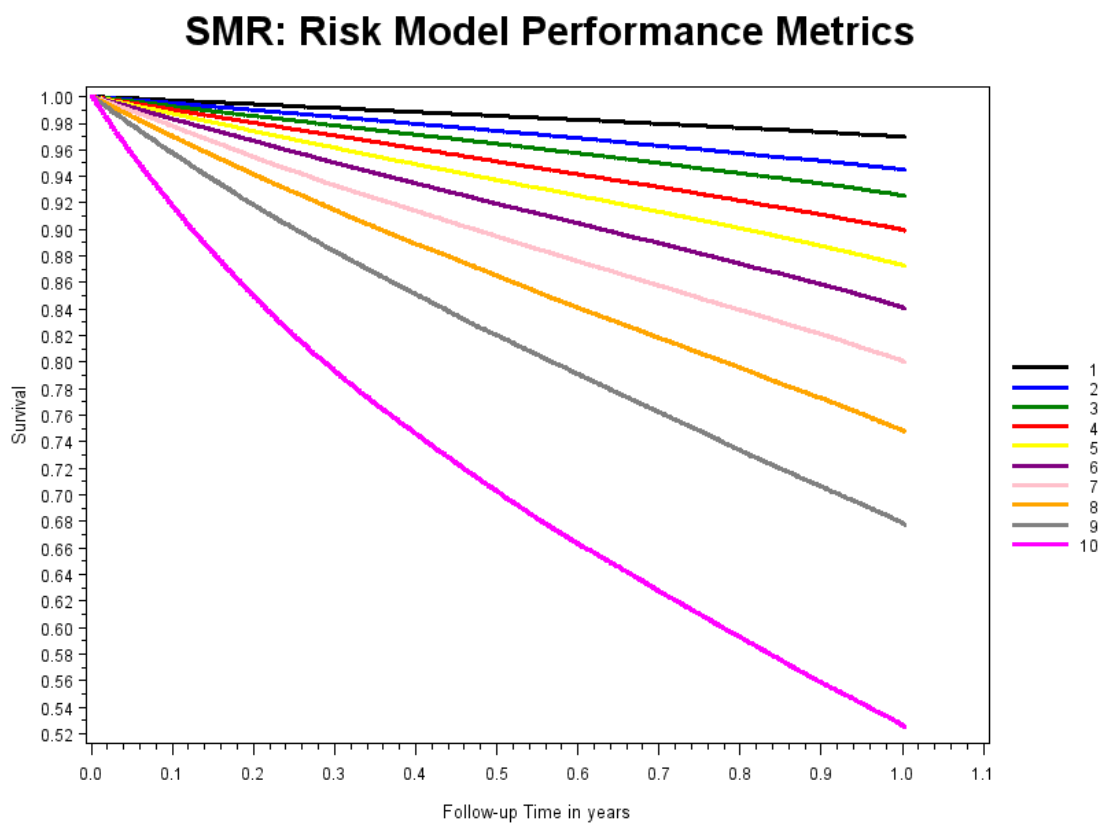
#### 2b4.9. Results of Risk stratification Analysis

N/A

#### 2b4.10. Interpretation

Figure 7 is the decile plot showing estimates of cumulative rates by years. The plot shows that the risk factors in the model are discriminating well between patients. There is good separation among all 10 groups and the ordering is as predicted by the model (patients predicted to be at lower risk have the best survival rates). The absolute differences between the groups is also large with survival at one year ranging from 96% for those patients predicted to have the lowest mortality rates (group 1) down to 60% for those predicted to have the lowest rates of survival (group 10).

**Figure 7.** Decile plot for SMR



#### 2b4.11. Optional Additional Testing for Risk Adjustment

N/A

## 2b5—Identification of statistically significant and clinically meaningful differences

### 2b5.1. Method for determining

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

### 2b5.2. Statistical Results

**Table 4.** Number and percentage of facilities by classification of the 2013 SMR. Categories stratified by facility size.

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

**Table 5.** Number and percentage of facilities by classification of the 2010-2013 SMR. Categories stratified by facility size.

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

### 2b5.3. Interpretation

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

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

## 2b6—Comparability of performance scores

### 2b6.1. Method of testing conducted to demonstrate comparability

N/A

#### 2b6.2. Statistical Results

N/A

#### 2b6.3. Interpretation

N/A

### ***Feasibility***

#### 3a.1. How are the data elements needed to compute measure scores generated

Generated "or collected" by and used by healthcare personnel during the provision of care (e.g., blood pressure, lab value, diagnosis, "depression score")

#### 3b.1. Are the data elements needed for the measure as specified available electronically

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

#### 3b.3. If this is an eMeasure, provide a summary of the feasibility assessment

N/A

#### 3c.1. Describe what you have learned or modified as a result of testing

Mortality measures have been in use in the Dialysis Facility Reports since 1995. Data are derived from various existing data bases as described earlier.

Information on death is obtained from several sources which include the Renal Beneficiary and Utilization System (REMIS), the Death Notification Form (Form CMS-2746), and the Social Security Death Master File (SSDMF). The SSDMF is used to supplement death information (1% of deaths).

This method for combining SSDMF with other sources of death data has been validated for use of death data on 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. This validated method also applies to death data used for SMR.

#### 3c.2. Describe any fees, licensing, or other requirements

N/A



## ***Usability and Use***

### **4.1—Current and Planned Use**

4a.1. Program, sponsor, purpose, geographic area, accountable entities, patients

Public Reporting: Dialysis Facility Compare (DFC)

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

Geographic area: United States

Number of accountable entities: All Medicare-certified dialysis facilities who are eligible for the measure, and have at least 3 expected deaths during 2010-2013. For the most recent DFC report, that was 5916 facilities.

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

4a.2. If not publicly reported or used for accountability, reasons

N/A

4a.3. If not, provide a credible plan for implementation

N/A

4b.1. Progress on improvement

Mortality rates have decreased over time as evidenced by the coefficients for calendar year from the SMR model (below, and in tabular format in the appendix). The mortality rate for 2011 was 2.6% lower compared to 2010 (p-value<0.0001), and the rates for 2012 and 2013 were lower compared to 2010 at 12.4% and 13.0%, respectively (p-value <0.0001).

2011: Coefficient = -0.026, P-value = <0.0001

2012: Coefficient = -0.124, P-value = <0.0001

2013: Coefficient = -0.130, P-value = <0.0001

4b.2. If no improvement was demonstrated, what are the reasons

N/A

## ***Related and Competing Measures***

### **5—Relation to Other NQF-Endorsed Measures**

5.1a. The measure titles and NQF numbers are listed here

#2496: Standardized Readmission Ratio for Dialysis Facilities

#1463: Standardized Hospitalization Ratio

5.1b. If the measures are not NQF-endorsed, indicate the measure title

N/A

### **5a—Harmonization**

5a.1. Are the measure specifications completely harmonized

No

5a.2. If not completely harmonized, identify the differences rationale, and impact

The specifications are not completely harmonized. Each measure assesses different outcomes as reflected in certain differences across the measure specifications. SMR, and SHR and SRR are harmonized to the population they measure (Medicare-covered ESRD patients), methods (SMR and SHR) and certain risk adjustment factors specific to the ESRD population. SMR and SHR adjust for the same comorbidity risk factors, a similar set of patient characteristics, and use fixed effects in their modeling approach.

The differences between SMR and SHR and SRR reflect adjustment for factors specific to the outcome of each respective measure. Both SMR and SHR adjust for a set of prevalent comorbidities (observed in a prior year), however the complete set of comorbidities for SMR differs from SRR. SRR, a measure of hospital utilization adjusts for planned readmissions; and for discharging hospital, acknowledging that for readmission, hospitals also bear accountability for properly coordinating care with the dialysis facility. These risk adjustments in SRR account for those characteristics specifically associated with readmission, and do not apply to SMR.

Only SMR adjusts for state death rates, race, and ethnicity to account for these respective differences related to mortality outcomes and that are deemed outside of a facility's control.

### **5b—Competing measures**

5b.1 Describe why this measure is superior to competing measures

N/A

## ***Additional Information***

### **Co.1.—Measure Steward Point of Contact**

Co.1.1. Organization

Centers for Medicare & Medicaid Services

Co.1.2. First Name

Sophia

Co.1.3. Last Name

Chan

Co.1.4. Email Address

sophia.chan@cms.hhs.gov

Co.1.5. Phone Number

410-786-5050

**Co.2.—Developer Point of Contact (indicate if same as Measure Steward Point of Contact)**

Co.2.1. Organization

University of Michigan Kidney Epidemiology and Cost Center

Co.2.2. First Name

Casey

Co.2.3. Last Name

Parrotte

Co.2.4. Email Address

parrotte@med.umich.edu

Co.2.5. Phone Number

734-763-6611

**Ad.1. Workgroup/Expert Panel Involved in Measure Development**

The following is a list of TEP members who participated in the End-Stage Renal Disease Evaluation of Potential Prevalent Comorbidity Adjustments in the Standardized Hospitalization Ratio (SHR) and the Standardized Mortality Ratio (SMR) TEP. In their advisory role, the primary duty of the TEP was to review any existing measures in terms of comorbidities included as adjusters, and determine if there was sufficient evidence to support the inclusion of specific proposed comorbidities as measure adjusters, and relatedly, suggest measure specifications.

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

Dana Miskulin, MD, MS  
Staff Nephrologist  
Tufts Medical Center  
Boston, MA  
Associate Professor of Medicine  
Outcomes Monitoring Program, Dialysis Clinic Inc.  
Nashville, TN

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

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

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

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

Mark Mitsnefes, MD, MS  
Professor of Pediatrics  
Cincinnati Children's Hospital Medical Center  
Program Director  
University of Cincinnati  
Cincinnati, OH

Roberta Wager, MSN, RN  
Renal Care Coordinator  
Fresenius Medical Care  
Member of Forum of ESRD Networks Beneficiary Council  
Forum of ESRD Networks  
Boerne, TX

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

**Ad.2. Year the Measure Was First Released**

**Ad.3. Month and Year of Most Recent Revision**

**Ad.4. What is your frequency for review/update of this measure?**

**Ad.5. When is your next scheduled review/update for this measure?**

**Ad.6. Copyright Statement**

**Ad.7. Disclaimers**

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

## 2a2.2. Method of Reliability Testing

Here we describe our approach to calculating IUR. Let  $T_1, \dots, T_N$  be the SMR for these facilities. Within each facility, select at random and with replacement  $B$  (say 100) bootstrap samples. That is, if the  $i$ th facility has  $n_i$  subjects, randomly draw with replacement  $n_i$  subjects from those in the same facility, find their corresponding SMR $_i$  and repeat the process  $B$  times. Thus, for the  $i$ th facility, we have bootstrapped SMRs of  $T_{i1}^*, \dots, T_{i200}^*$ . Let  $S_i^*$  be the sample variance of this bootstrap sample. From this it can be seen that

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

is a bootstrap estimate of the within-facility variance in the SMR, namely,  $\sigma_{t,w}^2$ . Calling on formulas from the one way analysis of variance, an estimate of the overall variance of  $T_i$  is

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

where

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

is the weighted mean of the observed SMR and

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

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

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

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