

Measure Justification Form

Project Title:

Standardized Hospitalization 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 hospitalization 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 Standardized Hospitalization Ratio for Admissions

Type of Measure Outcome

Importance

1a—Opportunity for Improvement

1a.1. This is a Measure of

Health outcome: Hospitalization

1a.2.—Linkage

1a.2.1 Rationale

Hospitalization rates remain very high in US chronic dialysis patients relative to the general population, despite a nearly 20% decline from 2005-2013. This trend in lower hospitalization is in contrast to the relatively stable hospitalization rates for the US general population over the same time period, suggesting that dialysis providers have been somewhat successful in reducing unnecessary hospitalizations through quality care improvements.

According to the 2015 USRDS Annual Report, approximately ½ of all dialysis patient hospitalizations continue to be caused by cardiovascular or infectious causes over that time period [1]. Recent research points to many additional opportunities to further reduce unnecessary hospitalization in this population.

Programs developed to impact dialysis provider practices have been shown to improve intermediate outcomes (reduced catheter vascular access, small solute adequacy, anemia management) and mortality, modality options, infection prevention, and dialysis organization culture [2-19]. These practice improvements have been linked to reduced hospitalizations in this population. For example, one study examined dialysis provider interventions targeting incident patients in order to improve outcomes for these patients that are at particularly high risk for poor outcomes that can lead to higher morbidity and mortality [2]. The results suggested improved on clinical outcomes in percentage of incident patients having a preferred vascular access type. In turn this has the potential to reduce hospitalization risk, along with mortality; other work on vascular access type also supports the link between access type and hospitalization, specifically due to chronic catheter use [3].

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] Wilson SM, Robertson JA, Chen G, Goel P, Benner DA, Krishnan M, Mayne TJ, Nissenson AR. The IMPACT (Incident Management of Patients, Actions Centered on Treatment) Program: A Quality Improvement Approach for Caring for Patients Initiating Long-term Hemodialysis. Am J Kidney Dis 60(3): 435-443, 2012

BACKGROUND: Patients beginning dialysis therapy are at risk of death and illness. The IMPACT (Incident Management of Patients, Actions Centered on Treatment) quality improvement program was developed to improve incident hemodialysis patient outcomes through standardized care.

STUDY DESIGN: Quality improvement report.

SETTING & PARTICIPANTS: Patients who started hemodialysis therapy between September 2007 and December 2008 at DaVita facilities using the IMPACT program (n = 1,212) constituted the intervention group. Propensity score-matched patients who initiated hemodialysis therapy in the same interval at DaVita facilities not using the IMPACT program (n = 2,424) made up the control group.

QUALITY IMPROVEMENT PLAN: IMPACT intervention included a structured intake process and monitoring reports; patient enrollment in a 90-day patient education program and 90-day patient management pathway.

OUTCOMES: Mean dialysis adequacy (Kt/V), hemoglobin and albumin levels, percentage of patients using preferred vascular access (arteriovenous fistula or graft), and mortality at each quarter.

RESULTS: Compared with the non-IMPACT group, the IMPACT group was associated with a higher proportion of patients dialyzing with a preferred access at 90 days (0.50 [95% CI, 0.47-0.53] vs 0.47 [95% CI, 0.45-0.49]; P = 0.1) and 360 days (0.63 [95% CI, 0.61-0.66] vs 0.48 [95% CI, 0.46-0.50]; P < 0.001) and a lower mortality rate at 90 days (24.8 [95% CI, 19.0-30.7] vs 31.9 [95% CI, 27.1-36.6] deaths/100 patient-years; P = 0.08) and 360 days (17.8 [95% CI, 15.2-20.4] vs 25.1 [95% CI, 20.7-25.2] deaths/100 patient-years; P = 0.01).

LIMITATIONS: The study does not determine the care processes responsible for the improved outcomes.

CONCLUSIONS: Intense management of incident dialysis patients with the IMPACT quality improvement program was associated with significantly decreased first-year mortality. Focused attention to the care of incident patients is an important part of a dialysis program.

[3] Vassalotti JA, Jennings WC, Beathard GA, Neumann M, Caponi S, Fox CH, Spergel LM and the Fistula First Breakthrough Initiative Community Education Committee. Fistula First Breakthrough Initiative: Targeting Catheter Last in Fistula First. *Seminars Dialysis* 25(3):303-310, 2012

Abstract: An arteriovenous fistula (AVF) is the optimal vascular access for hemodialysis (HD), because it is associated with prolonged survival, fewer infections, lower hospitalization rates, and reduced costs. The AVF First breakthrough initiative (FFBI) has made dramatic progress, effectively promoting the increase in the national AVF prevalence since the program's inception from 32% in May 2003 to nearly 60% in 2011. Central venous catheter (CVC) use has stabilized and recently decreased slightly for prevalent patients (treated more than 90 days), while CVC usage in the first 90 days remains unacceptably high at nearly 80%. This high prevalence of CVC utilization suggests important specific improvement goals for FFBI. In addition to the current 66% AVF goal, the initiative should include specific CVC usage target(s), based on the KDOQI goal of less than 10% in patients undergoing HD for more than 90 days, and a substantially improved

initial target from the current CVC proportion. These specific CVC targets would be disseminated through the ESRD networks to individual dialysis facilities, further emphasizing CVC avoidance in the transition from advanced CKD to chronic kidney failure, while continuing to decrease CVC by prompt conversion of CVC-based hemodialysis patients to permanent vascular access, utilizing an AVF whenever feasible.

[4] Ng LJ, Chen F, Pisoni RL, Krishnan M, Mapes D, Keen M, Bradbury BD. Hospitalization risks related to vascular access type among incident US hemodialysis patients. *Nephrol Dial Transplant*. 26(11):3659-66, 2011

BACKGROUND: The excess morbidity and mortality related to catheter utilization at and immediately following dialysis initiation may simply be a proxy for poor prognosis. We examined hospitalization burden related to vascular access (VA) type among incident patients who received some predialysis care.

METHODS: We identified a random sample of incident US Dialysis Outcomes and Practice Patterns Study hemodialysis patients (1996-2004) who reported predialysis nephrologist care. VA utilization was assessed at baseline and throughout the first 6 months on dialysis. Poisson regression was used to estimate the risk of all-cause and cause-specific hospitalizations during the first 6 months.

RESULTS: Among 2635 incident patients, 60% were dialyzing with a catheter, 22% with a graft and 18% with a fistula at baseline. Compared to fistulae, baseline catheter use was associated with an increased risk of all-cause hospitalization [adjusted relative risk (RR) = 1.30, 95% confidence interval (CI): 1.09-1.54] and graft use was not (RR = 1.07, 95% CI: 0.89-1.28). Allowing for VA changes over time, the risk of catheter versus fistula use was more pronounced (RR = 1.72, 95% CI: 1.42-2.08) and increased slightly for graft use (RR = 1.15, 95% CI: 0.94-1.41). Baseline catheter use was most strongly related to infection-related (RR = 1.47, 95% CI: 0.92-2.36) and VA-related hospitalizations (RR = 1.49, 95% CI: 1.06-2.11). These effects were further strengthened when VA use was allowed to vary over time (RR = 2.31, 95% CI: 1.48-3.61 and RR = 3.10, 95% CI: 1.95-4.91, respectively). A similar pattern was noted for VA-related hospitalizations with graft use. **Discussion.** Among potentially healthier incident patients, hospitalization risk, particularly infection and VA-related, was highest for patients dialyzing with a catheter at initiation and throughout follow-up, providing further support to clinical practice recommendations to minimize catheter placement.

[5] 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. *CJASN* 8:2132-2140, 2013.

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.

[6] Pun PH, Horton JR, Middleton JP. Dialysate calcium concentration and the risk of sudden cardiac arrest in hemodialysis patients. *CJASN* 8:797-803, 2013.

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.

[7] 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.* 10(1):90-7, 2015.

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

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

RESULTS: Of 4435 patients who underwent parathyroidectomy, 2.0% died during the parathyroidectomy hospitalization and the 30 days after discharge. During the 30 days after discharge, 23.8% of patients were rehospitalized; 29.3% of these patients required intensive care. In the year after parathyroidectomy, hospitalizations were higher by 39%, hospital days by 58%, intensive care unit admissions by 69%, and emergency room/observation visits requiring hypocalcemia treatment by 20-fold compared with the preceding year. Cause-specific hospitalizations were higher for acute myocardial infarction (rate ratio, 1.98; 95% confidence interval, 1.60 to 2.46) and dysrhythmia (rate ratio 1.4; 95% confidence 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.

[8] Tentori F, McCullough K, Kilpatrick RD, Bradbury BD, Robinson BM, Kerr PG, Pisoni RL. High rates of death and hospitalization follow bone fracture among hemodialysis patients. *Kidney Int.* 85(1):166-73, 2014.

Abstract: Altered bone structure and function contribute to the high rates of fractures in dialysis patients compared to the general population. Fracture events may increase the risk of subsequent adverse clinical outcomes. Here we assessed the incidence of post-fracture morbidity and mortality in an international cohort of 34,579 in-center hemodialysis patients in the Dialysis Outcomes and Practice Patterns Study (DOPPS). We estimated country-specific rates of fractures requiring a hospital admission and associated length of stay in the hospital.

Incidence rates of death and of a composite event of death/rehospitalization were estimated for 1 year after fracture. Overall, 3% of participants experienced a fracture. Fracture incidence varied across countries, from 12 events/1000 patient-years (PY) in Japan to 45/1000 PY in Belgium. In all countries, fracture rates were higher in the hemodialysis group compared to those reported for the general population. Median length of stay ranged from 7 to 37 days in the United States and Japan, respectively. In most countries, postfracture mortality rates exceeded 500/1000 PY and death/rehospitalization rates exceeded 1500/1000 PY. Fracture patients had higher unadjusted rates of death (3.7-fold) and death/rehospitalization (4.0-fold) compared to the overall DOPPS population. Mortality and hospitalization rates were highest in the first month after the fracture and declined thereafter. Thus, the high frequency of fractures and increased adverse outcomes following a fracture pose a significant health burden for dialysis patients. Fracture prevention strategies should be identified and applied broadly in nephrology practices.

[9] Weinhandl ED, Arneson TJ, St Peter WL. Clinical outcomes associated with receipt of integrated pharmacy services by hemodialysis patients: a quality improvement report. *Am J Kidney Dis.* Sep;62(3):557-67, 2013.

Reducing medication-related problems and improving medication adherence in hemodialysis patients may improve clinical outcomes. In 2005, a large US dialysis organization created an integrated pharmacy program for its patients. We aimed to compare the outcomes of hemodialysis patients enrolled in this program and matched control patients.

STUDY DESIGN: Quality improvement report.

SETTING & PARTICIPANTS: Hemodialysis patients with concurrent Medicare and Medicaid eligibility who chose to receive program services and propensity score-matched controls; the propensity score was an estimated function of demographic characteristics, comorbid conditions, medication exposure, serum concentrations, and vascular access method.

QUALITY IMPROVEMENT PLAN: Program services included medication delivery, refill management, medication list reviews, telephonic medication therapy management, and prior authorization assistance.

OUTCOMES: Relative rates of death and hospitalization.

MEASUREMENTS: Survival estimates calculated with the Kaplan-Meier method; mortality hazards compared with Cox regression; hospitalization rates compared with Poisson regression.

RESULTS: In outcome models, there were 8,864 patients receiving integrated pharmacy services and 43,013 matched controls. In intention-to-treat and as-treated analyses, mortality HRs for patients receiving integrated pharmacy services versus matched controls were 0.92 (95% CI, 0.86-0.97) and 0.79 (95% CI, 0.74-0.84), respectively. Corresponding relative rates of hospital admissions were 0.98 (95% CI, 0.95-1.01) and 0.93 (95% CI, 0.90-0.96), respectively, and of hospital days, 0.94 (95% CI, 0.90-0.98) and 0.86 (95% CI, 0.82-0.90), respectively. Cumulative incidences of disenrollment from the pharmacy program were 23.4% at 12 months and 37.0% at 24 months.

LIMITATIONS: Patients were not randomly assigned to receive integrated pharmacy services; as-treated analyses may be biased because of informative censoring by disenrollment from the pharmacy program; data regarding use of integrated pharmacy services were lacking.

CONCLUSIONS: Receipt of integrated pharmacy services was associated with lower rates of death and hospitalization in hemodialysis patients with concurrent Medicare and Medicaid eligibility. Studies are needed to measure pharmacy program use and assess detailed clinical and economic outcomes.

[10]. Weinhandl ED, Gilbertson DT, Collins AJ. Mortality, Hospitalization, and Technique Failure in Daily Home Hemodialysis and Matched Peritoneal Dialysis Patients: A-†Matched Cohort Study. *Am J Kidney Dis.* 67(1):98-110, 2016.

BACKGROUND: Use of home dialysis is growing in the United States, but few direct comparisons of major clinical outcomes on daily home hemodialysis (HHD) versus peritoneal dialysis (PD) exist.

STUDY DESIGN: Matched cohort study.

SETTING & PARTICIPANTS: We matched 4,201 new HHD patients in 2007 to 2010 with 4,201 new PD patients from the US Renal Data System database.

PREDICTOR: Daily HHD versus PD.

OUTCOMES: Relative mortality, hospitalization, and technique failure.

RESULTS: Mean time from end-stage renal disease onset to home dialysis therapy initiation was 44.6 months for HHD and 44.3 months for PD patients. In intention-to-treat analysis, HHD was associated with 20% lower risk for all-cause mortality (HR, 0.80; 95% CI, 0.73-0.87), 8% lower risk for all-cause hospitalization (HR, 0.92; 95% CI, 0.89-0.95), and 37% lower risk for technique failure (HR, 0.63; 95% CI, 0.58-0.68), all relative to PD. In the subset of 1,368 patients who initiated home dialysis therapy within 6 months of end-stage renal disease onset, HHD was associated with similar risk for all-cause mortality (HR, 0.95; 95% CI, 0.80-1.13), similar risk for all-cause hospitalization (HR, 0.96; 95% CI, 0.88-1.05), and 30% lower risk for technique failure (HR, 0.70; 95% CI, 0.60-0.82). Regarding hospitalization, risk comparisons favored HHD for cardiovascular disease and dialysis access infection and PD for bloodstream infection.

LIMITATIONS: Matching unlikely to reduce confounding attributable to unmeasured factors, including residual kidney function; lack of data regarding dialysis frequency, duration, and dose in daily HHD patients and frequency and solution in PD patients; diagnosis codes used to classify admissions.

CONCLUSIONS: These data suggest that relative to PD, daily HHD is associated with decreased mortality, hospitalization, and technique failure. However, risks for mortality and hospitalization were similar with these modalities in new dialysis patients. The interaction between modality and end-stage renal disease duration at home dialysis therapy initiation should be investigated further.

[11] Rosenblum A, Wang W, Ball LK, Latham C, Maddux FW, Lacson E. Hemodialysis catheter care strategies: A cluster-randomized quality improvement initiative. *Am J Kidney Dis.* 63(2):259-267, 2014.

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.

[12] Patel PR, Kallen AJ. Bloodstream infection prevention in ESRD: Forging a pathway for success. *Am J Kidney Dis.* 63(2):180-182, 2014

Introduction: There should be little doubt regarding the importance of infections in the hemodialysis patient population. For years, the US Renal Data System has reported increasing hospitalization rates for all infectious diagnoses and for bacteremia/sepsis in patients treated with hemodialysis.¹ In 2011, the Centers for Disease Control and Prevention (CDC) reported that although the burden of central line-associated bloodstream infections (BSIs) in hospitalized

patients had declined nationally, the estimated burden of central line–associated BSIs in people treated with outpatient hemodialysis was substantial, possibly reaching 37,000 in 2008.² Soon after, the US Department of Health and Human Services released their National Action Plan to Prevent Healthcare-Associated Infections (HAIs) for End Stage Renal Disease (ESRD) Facilities.³ The Action Plan, which was developed by the Federal Steering Committee for the Prevention of HAIs in ESRD Facilities with dialysis community stakeholder input, highlighted BSIs as a top priority for national prevention efforts.

[13] Gilbertson DT, Guo H, Arneson TJ, Collins AJ. The association of pneumococcal vaccination with hospitalization and mortality in hemodialysis patients. *Nephrol Dial Transplant*. Sept;26(9):2934-9, 2011.

BACKGROUND: Few studies have examined the effectiveness of pneumococcal vaccination (alone or with influenza vaccination) in improving hemodialysis patient outcomes. We aimed to describe vaccination rates between 2003-2005 and to study the effects on outcomes.

METHODS: For 118,533 prevalent patients who initiated hemodialysis ≥ 90 days before 1 November 2003, had Medicare Part A and Part B and were aged ≥ 18 years, and alive through 31 October 2005, Cox proportional hazards models were used to assess pneumococcal vaccination effects on subsequent hospitalization and mortality, adjusting for demographics and comorbidity.

RESULTS: The 21% of patients who received vaccinations were older; a higher proportion were white, with diabetes as cause of end-stage renal disease and more comorbidity. Pneumococcal vaccination was associated with a statistically significant decreased mortality hazard [hazard ratio (HR) 0.94, 95% confidence interval (CI) 0.90-0.98], cardiac death (HR 0.91, 95% CI 0.85-0.97) and hospitalization for bacteremia/viremia/septicemia (HR 0.95, 95% CI 0.91-1.00). The mortality hazard was 0.73 (95% CI 0.68-0.78) for patients who received pneumococcal and influenza vaccinations.

CONCLUSIONS: The small but significant association between pneumococcal vaccination and lower mortality risk was seen despite factors associated with poor outcomes in patients most likely to be vaccinated. Pneumococcal and influenza vaccines may have beneficial synergistic effects. Hemodialysis patients may benefit from revaccination more frequently than the recommended 5-year intervals.

[14] Dalrymple LS, Mu Y, Nguyen DV, Romano PS, Chertow GM, Grimes B, Kaysen GA, Johansen KL. *CJASN* 10:2170-2180, 2015.

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

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

examine the associations among patient and dialysis facility characteristics and the rate of infection-related hospitalization.

RESULTS: Among 135,545 Medicare beneficiaries, 38,475 (28%) had at least one infection-related hospitalization. The overall rate of infection-related hospitalization was 40.2 per 100 person-years. Age ≥ 85 years old, cancer, chronic obstructive pulmonary disease, inability to ambulate or transfer, drug dependence, residence in a care facility, serum albumin < 3.5 g/dl at dialysis initiation, and dialysis initiation with an access other than a fistula were associated with a $\geq 20\%$ 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.

[15] Gilbertson DT, Wetmore JB. Infections Requiring Hospitalization in Patients on Hemodialysis CJASN 10:2101-2103, 2015.

Introduction: Although the past decade has witnessed significant improvements in survival or patients receiving hemodialysis (HD) (1), hospitalization rates, particularly for infection, have not improved commensurately. Notable lack of progress is evident regarding hospitalizations for bacteremia/septicemia and pulmonary infections, such as pneumonia and influenza (2). For bacteremia/septicemia, first-year (incident) admission rates showed a 39% relative increase between 2003 and 2010 from 12.9% to 18.0%. Similarly, admission rates for prevalent patients increased 36% from 8.6% to 11.6%. Pneumonia/influenza hospitalization rates also did not improve between 2003 and 2010; although first-year admission rates decreased slightly (from 10.2% to 9.0%), rates for prevalent patients increased from 8.3% to 9.0%.

[16] Arneson TJ, Liu J, Qiu Y, Gilbertson DT, Foley RN, Collins AJ. Hospital treatment for fluid overload in the Medicare hemodialysis population. Clin J Am Soc Nephrol.(6):1054-63, 2010.

BACKGROUND AND OBJECTIVES: Fluid overload in hemodialysis patients sometimes requires emergent dialysis, but the magnitude of this care has not been characterized. This study aimed to estimate the magnitude of fluid overload treatment episodes for the Medicare hemodialysis population in hospital settings, including emergency departments.

DESIGN, SETTING, PARTICIPANTS, & MEASUREMENTS: Point-prevalent hemodialysis patients were identified from the Centers for Medicare and Medicaid Renal Management Information System and Standard Analytical Files. Fluid overload treatment episodes were defined by claims for care in inpatient, hospital observation, or emergency department settings with primary discharge diagnoses of fluid overload, heart failure, or pulmonary edema, and dialysis performed on the day of or after admission. Exclusion criteria included stays > 5 days. Cost was defined as total Medicare allowable costs for identified episodes. Associations between patient characteristics and episode occurrence and cost were analyzed.

RESULTS: For 25,291 patients (14.3%), 41,699 care episodes occurred over a mean follow-up time of 2 years: 86% inpatient, 9% emergency department, and 5% hospital observation. Heart failure was the primary diagnosis in 83% of episodes, fluid overload in 11%, and pulmonary edema in 6%. Characteristics associated with more frequent events included age <45 years, female sex, African-American race, causes of ESRD other than diabetes, dialysis duration of 1 to 3 years, fewer dialysis sessions per week at baseline, hospitalizations during baseline, and most comorbid conditions. Average cost was \$6,372 per episode; total costs were approximately \$266 million.

CONCLUSIONS: Among U.S. hemodialysis patients, fluid overload treatment is common and expensive. Further study is necessary to identify prevention opportunities.

[17] Erickson KF, Winkelmayer WC, Chertow GM, Bhattacharya J. Physician visits and 30-day hospital readmissions in patients receiving hemodialysis. *J Am Soc Nephrol* 25:2079-2087, 2014.

Abstract: A focus of health care reform has been on reducing 30-day hospital readmissions. Patients with ESRD are at high risk for hospital readmission. It is unknown whether more monitoring by outpatient providers can reduce hospital readmissions in patients receiving hemodialysis. In nationally representative cohorts of patients in the United States receiving in-center hemodialysis between 2004 and 2009, we used a quasi-experimental (instrumental variable) approach to assess the relationship between frequency of visits to patients receiving hemodialysis following hospital discharge and the probability of rehospitalization. We then used a multivariable regression model and published hospitalization data to estimate the cost savings and number of hospitalizations that could be prevented annually with additional provider visits to patients in the month following hospitalization. In the main cohort (n=26,613), one additional provider visit in the month following hospital discharge was estimated to reduce the absolute probability of 30-day hospital readmission by 3.5% (95% confidence interval, 1.6% to 5.3%). The reduction in 30-day hospital readmission ranged from 0.5% to 4.9% in an additional four cohorts tested, depending on population density around facilities, facility profit status, and patient Medicaid eligibility. At current Medicare reimbursement rates, the effort to visit patients one additional time in the month following hospital discharge could lead to 31,370 fewer hospitalizations per year, and \$240 million per year saved. In conclusion, more frequent physician visits following hospital discharge are estimated to reduce rehospitalizations in patients undergoing hemodialysis. Incentives for closer outpatient monitoring following hospital discharge could lead to substantial cost savings.

[18] Klinger AS. Maintaining safety in the dialysis facility. *CJASN* 10:688-695, 2015.

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.

[19] Nissenson AR. Improving outcomes for ESRD patients: Shifting the quality paradigm. CJASN 9:430-434, 2014.

Abstract: The availability of life-saving dialysis therapy has been one of the great successes of medicine in the past four decades. Over this time period, despite treatment of hundreds of thousands of patients, the overall quality of life for patients with ESRD has not substantially improved. A narrow focus by clinicians and regulators on basic indicators of care, like dialysis adequacy and anemia, has consumed time and resources but not resulted in significantly improved survival; also, frequent hospitalizations and dissatisfaction with the care experience continue to be seen. A new quality paradigm is needed to help guide clinicians, providers, and regulators to ensure that patients' lives are improved by the technically complex and costly therapy that they are receiving. This paradigm can be envisioned as a quality pyramid: the foundation is the basic indicators (outstanding performance on these indicators is necessary but not sufficient to drive the primary outcomes). Overall, these basics are being well managed currently, but there remains an excessive focus on them, largely because of publically reported data and regulatory requirements. With a strong foundation, it is now time to focus on the more complex intermediate clinical outcomes-fluid management, infection control, diabetes management, medication management, and end-of-life care among others. Successfully addressing these intermediate outcomes will drive improvements in the primary outcomes, better survival, fewer hospitalizations, better patient experience with the treatment, and ultimately, improved quality of life. By articulating this view of quality in the ESRD program (pushing up the quality pyramid), the discussion about quality is reframed, and also, clinicians can better target their facilities in the direction of regulatory oversight and requirements about quality. Clinicians owe it to their patients, as the ESRD program celebrates its 40th anniversary, to rekindle the aspirations of the creators of the program, whose primary goal was to improve the lives of the patients afflicted with this devastating condition.

1a.3.—LinkageUS

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

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

1a.6.1. Review Citation

N/A

1a.6.2. Methodology Citation

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

Hospitalization rates are an important indicator of patient morbidity and quality of life. On average, dialysis patients are admitted to the hospital nearly twice a year and spend an average of 11.2 days in the hospital per year [1]. Hospitalizations account for approximately 40 percent of total Medicare expenditures for ESRD patients [1]. Measures of the frequency of hospitalization have the potential to help efforts to control escalating medical costs, and to play an important role in identifying potential problems and helping facilities provide cost-effective health care.

[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.

1b.2. Performance Scores

Standardized hospitalization admission rates vary widely across facilities. For example, for 2013, the SHR Admissions varied from 0.07 to 2.92. The mean value was 0.99 and the SD was 0.27. The data used to calculate these rates is limited to those facilities with at least 5 patient years at risk (reflecting how the measure is currently calculated on DFC).

Distribution of the SHR, 2010-2013

2010: Mean = 0.99, Std Dev = 0.28, Min = 0.06, Max = 3.32

2011: Mean = 0.99, Std Dev = 0.28, Min = 0.18, Max = 3.51

2012: Mean = 0.99, Std Dev = 0.27, Min = 0.16, Max = 3.09

2013: Mean = 0.99, Std Dev = 0.27, Min = 0.07, Max = 2.92

1b.3. Summary of Data Indicating Opportunity

N/A

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

Race and ethnicity have been shown to be predictors of hospitalization. Using data from 2013, it is observed that white and black patients are hospitalized at similar rates (both SHRs = 1.01). Native American and Asian/Pacific Islander patients are hospitalized at lower rates than would be expected (SHR = 0.90 and 0.84, respectively). Also, Hispanic patients had slightly lower than expected hospitalization rates (SHR = 0.98), while non-Hispanic and patients of unknown ethnicity were hospitalized at the same rate (both SHRs = 1.00). While there are slight differences across the respective race and ethnicity groups the results suggest no clear disparities in outcomes and that it would not be appropriate to adjust for these factors. Several arguments led to the exclusion of race and ethnicity as adjusters from SHR. First, if race is correlated with care quality, adjustment for race could tend to excuse poor quality care provided by dialysis facilities that leads to higher hospitalization rates, or mask differences in rates among races that may be attributed to care quality. Although unadjusted rates by race or ethnicity indicate slight differences between the groups, the inclusion of race, Hispanic ethnicity, Medicaid status at incidence (from CMS Form-2728) or socioeconomic status (defined for each patient as the median zip code household income) in alternative SHR models had little effect on the resulting expected admissions counts from the model.

Refer to Risk Adjustment section (2b4) for analyses on sex and socioeconomic status.

1c.—High Priority

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

Affects large numbers

Severity of illness

High resource use

1c.3. Epidemiologic or Resource Use Data

Hospitalization rates are an important indicator of patient morbidity and quality of life. On average, dialysis patients are admitted to the hospital twice a year and spend an average of 11.2 days in the hospital per year [1]. Hospitalizations account for approximately 40 percent of total Medicare expenditures for ESRD patients [1]. Measures of the frequency of hospitalization have the potential to help efforts to control escalating medical costs, and to play an important role in identifying potential problems and helping facilities provide cost-effective health care.

At the end of 2013 there were 661,648 patients being dialyzed, of which 117,162 were new (incident) ESRD patients [1]. In 2013, total Medicare costs for the ESRD program were \$30.9 billion, a 1.6% increase from 2012 [1]. Correspondingly, hospitalization costs for ESRD patients are very high with Medicare costs of over \$10.3 billion in 2013.

Hospitalization measures have been in use in the Dialysis Facility Reports (formerly Unit-Specific Reports) since 1995. 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. In particular, the SHR for Admissions is used by ESRD state surveyors in conjunction with other standard criteria for prioritizing and selecting facilities to survey and has been found to be predictive of citations in the past (ESRD State Outcomes List). The SHR is also a public reporting measure on the Centers for Medicare and Medicaid Services (CMS) Dialysis Facility Compare website.

As noted above, hospitalization among dialysis patients is common and accounts for a large fraction of Medicare expenditures for ESRD beneficiaries. The Agency for Healthcare Research and Quality (AHRQ) Prevention Quality Indicators (PQIs) has identified several diagnoses where timely and effective ambulatory care can significantly reduce hospitalization. These diagnoses represent hospitalizations that might be prevented with effective ambulatory care including but not limited to dialysis facilities. We identified the PQIs most common for ESRD patients and compared the frequency of those diagnoses for the ESRD population to that of the general Medicare population in the fee-for-service system. Based on clinical input we identified several other diagnoses common among dialysis patients that may be preventable through the delivery of appropriate dialysis care [2]. Our analysis showed that compared to the general Medicare population, ESRD patients were hospitalized at higher rates for the following potentially preventable conditions as defined by AHRQ PQIs: diabetes with long term complications (16 times the rate of the general Medicare population), lower extremity amputation (22 times), and diabetes with short term complications (22 times). Applying the ESRD-specific potentially preventable conditions, ESRD patients were hospitalized at a higher rate for the following: complications of device/implant/graft (ESRD-related only) (13 times), septicemia (except in labor) (7 times) and fluid and electrolyte disorder (8 times). Since for most dialysis patients the dialysis facility is the principal source of ambulatory care and may even be considered by some as their medical home, it is reasonable to expect that high quality care by the dialysis facility could reduce the very high rate of hospitalizations among dialysis patients. Further, the facility-level correlation between the hospitalization rate for potentially preventable hospitalizations and that for all hospitalizations (the SHR) was found in this study to be high (0.84 for facilities with more than 20 patient years). This result provides further evidence that facilities have opportunities to reduce hospitalizations through appropriate dialysis care [2].

A 2015 Technical Expert Panel closely reviewed comorbidities related to hospitalization and provided an assessment of each and the likelihood whether they were related to facility care. This assessment process and the results are further described in the risk adjustment section below.

1c.4. Citations

- [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] Wheeler J, Hirth R, Meyer K, Messana JM. Exploring preventable hospitalizations of dialysis patients. J Am Soc Nephrol 22, 2011.
- [3] Erickson KF, Winkelmayer WC, Chertow GM, Bhattacharya J. Physician visits and 30-day hospital readmissions in patients receiving hemodialysis. J Am Soc Nephrol 25, 2014 (published online before print).
- [4] Arora P, Kausz AT, Obrador GT, Ruthazer R, Khan S, Jenuleson CS, Meyer KB, Pereira BJ. Hospital utilization among chronic dialysis patients. J Am Soc Nephrol 11: 740–746, 2000.
- [5] Piraino B. Staphylococcus aureus infections in dialysis patients: focus on prevention. ASAIO J 46(6): S13-S17, 2000.
- [6] Dalrymple LS, Johansen KL, Romano PS, Chertow GM, Mu Y, Ishida JH, Grimes B, Kaysen GA, Nguyen DV. Comparison of hospitalization rates among for-profit and nonprofit dialysis facilities. Clin J Am Soc Nephrol 9, 2014 (published online before print).

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?

Calendar years 2010 through 2013

1.4. What Levels of Analysis Were Tested?

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 5,406, 5,582, 5,708 and 5,863 facilities, respectively.

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

Medicare dialysis patients were included in the testing and analysis for each of the four years from 2010-2013 of which there were 377,675, 387,249, 396,167 and 403,337 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 SHR was assessed using data among Medicare 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 SHR, 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 SHR calculation only included facilities with at least 5 patient years at risk.

2a2.3. Statistical Results from Reliability Testing

Overall, we found that IURs for the one-year SHRs have a range of 0.70-0.72 across the years 2010, 2011, 2012 and 2013, which indicates that two-thirds of the variation in the one-year SHR can be attributed to the between-facility differences and one-third to within-facility variation.

Table 1: IUR for One-year SHR, 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	0.72	5407	0.71	5583	0.70	5709	0.70	5864
Small (<=50)	0.54	1864	0.51	1921	0.48	1977	0.46	2028
Medium (51–87)	0.65	1702	0.63	1785	0.58	1825	0.57	1930
Large (>=88)	0.81	1841	0.81	1877	0.81	1907	0.82	1906

2a2.4. Interpretation

This value of IUR indicates a high 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

We have assessed the validity of the measure through various comparisons of this measure with other quality measures in use, using Spearman correlations. The measure is also maintained on face validity. Hospitalization measures were reviewed by a TEP in 2007 and overall measures based on admissions and on days were recommended for inclusion in the Dialysis Facility reports. 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. In addition, hospitalization is a major cost factor in the management of ESRD patients as noted earlier, further establishing a very strong case for face validity of the SHR admissions measure.

2b2.3. Statistical Results from Validity Testing

The SHR Admissions measure is correlated with the Standardized Mortality Ratio (SMR) for each individual year from 2010-2013, where Spearman's correlation coefficient ranged from 0.27 to 0.30, with all four correlations being highly significant ($p < 0.0001$). Also for each year from 2011-2013, the SHR was correlated with the Standardized Readmission Ratio (SRR) (Spearman's $\rho = 0.54, 0.50, 0.48$; $p < 0.0001$).

In addition, SHR Admissions is negatively correlated in each of the four-years with percent of patients in the facility with AV Fistula (Spearman's $\rho = -0.12, -0.15, -0.12, -0.13$). Thus higher values of SHR are associated with lower usage of AV Fistulas. Further, SHR admissions is positively correlated with catheter use (Spearman's $\rho = 0.21, 0.21, 0.18, 0.16$), indicating that higher values of SHR are associated with increased use of catheters. These correlations are all highly significant ($p < 0.001$). For each year of 2010 through 2013, the SHR Admissions is also found to be negatively correlated with the percent of hemodialysis patients with $Kt/V \geq 1.2$, again in the direction expected (Spearman's $\rho = -0.11, -0.13, -0.10, -0.11$; $p < 0.0001$). Lower SHRs are associated with a higher percentage of patients receiving adequate dialysis dose.

The SHR Admissions is an overall measure of hospital use and reflects many different causes or reasons for hospitalization. The 2007 TEP considered the possibility of developing cause specific SHRs, but recommended the use of all-cause SHR measures due to various reasons including the lack of clear research to indicate what causes (i.e., reason for admission) should be selected as indicative of poor ESRD care, and issues associated with inter-rater reliability in assessing cause of hospitalization. The TEP reached a strong consensus that the all-cause measure would be reliable and valid and the measure would typically be related to quality of care. We have some crude measures of cause of hospitalization which we have used to assess the relationship between the all-cause measure and cause specific components. These measures are useful in assessing the overall SHR measures, but we caution that the cause specific hospitalizations have not been tested or validated at this time. All correlations are in the expected direction and highly significant, ($p < 0.0001$). Thus these preliminary analyses show that the overall hospitalization rate also

correlates strongly with specific causes that are commonly thought to be potentially related to poor quality of care.

2b2.4. Interpretation

The SHR correlates strongly with outcomes, processes of care, and causes of hospitalization that are commonly thought to be potentially related to poor quality of care. Higher hospitalization was associated with higher facility mortality rates; and similarly with higher readmissions. We found higher values of SHR are associated with lower usage of AV Fistulas, and suboptimal dialysis adequacy, and higher catheter use.

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 229 risk factors (diabetes, sex, age, 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, diabetes, duration of ESRD, nursing home status, BMI at incidence, comorbidities at incidence, a set of prevalent comorbidities, and calendar year. In this model, covariates are taken to act multiplicatively on the admission 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), Kalbfleisch and Prentice (2002), Lawless and Nadeau (1995), Lin et al. (2000), Cook and Lawless (2007) and Liu, Schaubel and Kalbfleisch (2010). All analyses are done using SAS. The adjustments included in the model are all statistically significant in the model.

In general, adjustment factors for the SHR were selected based on several considerations. As noted above, we began with a large set of patient characteristics, including demographics, comorbidities at ESRD incidence, a set of prevalent comorbidities, and other characteristics. Factors considered

appropriate were then investigated with statistical models, including interactions between sets of adjusters, to determine if they were related to hospitalizations. Factors related to the SHR were also evaluated for face validity before being included.

First, in 2007, a Technical Expert Panel was convened; the TEP provided advice on various aspects of the SHR, including adjustment factors. The 2007 Hospitalization TEP felt that facility characteristics are generally not appropriate for use as adjusters, but should be evaluated for their potential as proxies for patient characteristics. They also recommended that facility market characteristics, such as local hospital utilization rates, should not be considered as risk adjusters. They recommended instead that regional comparisons be made available to increase understanding of differences across markets.

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 hospitalization. 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. This list of comorbidities are reflected in the risk-adjustment methodology and model results for this measure.

Adjustments for race, ethnicity and sociodemographic status

Including race, Hispanic ethnicity or socioeconomic status did not contribute more to the SHR compared to a model with most of the current set of adjusters (Figures 1-3 below). Therefore we did not adjust for these factors in the final model. We are currently examining other measures of SES and SDS to assess impact on expected hospitalization and whether it would be appropriate to adjust for these factors.

Adjustment for sex

Additionally, our analysis of medical evidence and claims data is generally supportive of the current approach to sex adjustment in the SHR. It is consistent with the consensus opinion that adjustment for sex is appropriate, in that there is some evidence of physiological cause for higher hospitalization rates among females.

2b4.4. Statistical Results

Model Coefficients

Table 2a. Model Coefficients, Data Years 2010–2013.

Covariate	Coefficient	P-value
Comorbidities at start of ESRD		
At least one of the comorbidities listed below	0.08624	<.0001
Atherosclerotic heart disease	0.04999	<.0001
Other cardiac disease	0.04395	<.0001
Diabetes*	-0.02026	<.0001
Congestive heart failure	0.04269	<.0001
Inability to ambulate	0.02042	<.0001
Chronic obstructive pulmonary disease	0.05646	<.0001
Inability to transfer	0.02401	<.0001
Malignant neoplasm, cancer	0.04102	<.0001
Peripheral vascular disease	0.04104	<.0001
Cerebrovascular disease, CVA, TIA	0.01904	<.0001
Tobacco use (current smoker)	0.08539	<.0001
Alcohol dependence	0.01285	0.036
Drug dependence	0.17361	<.0001
No Medical Evidence (CMS-2728) Form	0.15316	<.0001
Cause of ESRD		
Diabetes	0.03848	<.0001
Missing	-0.03547	<.0001
Sex: Female	0.07156	<.0001
Age		
0-14	0.48884	<.0001
15-24	0.13135	<.0001
25-44	-0.0678	<.0001
45-59	-0.065	<.0001
60-74	Reference	
75+	0.10178	<.0001
BMI		
Log BMI	-0.15032	<.0001
BMI missing	0.01656	0.0002
Calendar year		
2010	Reference	
2011	-0.02546	<.0001
2012	-0.12676	<.0001
2013	-0.16265	<.0001
In nursing home the previous year	0.20788	<.0001
Diabetes as cause of ESRD X time on ESRD interaction term		
91 days-6 months	Reference	
6 months-1 year	0.03417	<.0001
1-2 years	0.01166	0.0737
2-3 years	0.00139	0.8356
3-5 years	-0.01549	0.0147
5+ years	-0.06398	<.0001
Cause of ESRD: diabetes X sex: female interaction term	-0.02622	<.0001
Age X diabetes as cause of ESRD interaction term		
0-14	-0.93749	<.0001
15-24	0.16727	<.0001
25-44	0.15502	<.0001

Covariate	Coefficient	P-value
45-59	0.05013	<.0001
60-74	Reference	
75+	-0.03426	<.0001
Age X female sex interaction term		
0-14	-0.13038	0.0002
15-24	0.24562	<.0001
25-44	0.12877	<.0001
45-59	0.03139	<.0001
60-74	Reference	
75+	-0.00664	0.0685

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

Table 2b. Prevalent Comorbidity Coefficients, Data Years 2010–2013.

ICD-9 Description	ICD-9 Code	Coefficient	P-value
Protein-cal malnutr NOS	2639	0.10345	<.0001
Aut neuropthy in oth dis	3371	0.02621	<.0001
Epilep NOS w/o intr epil	34590	0.19176	<.0001
Cerebral edema	3485	0.09181	<.0001
Subendo infarct, initial	41071	0.18348	<.0001
AMI NEC, unspecified	41080	0.03986	0.0367
AMI NOS, unspecified	41090	-0.03149	<.0001
Intermed coronary synd	4111	0.2052	<.0001
Ac ischemic hrt dis NEC	41189	0.11644	<.0001
Angina pectoris NEC/NOS	4139	0.12568	<.0001
Cardiomyopath in oth dis	4258	0.16331	<.0001
Atriovent block complete	4260	0.02671	0.0001
Parox ventric tachycard	4271	0.09607	<.0001
Parox tachycardia NOS	4272	0.06145	<.0001
Atrial fibrillation	42731	0.13302	<.0001
Atrial flutter	42732	0.08346	<.0001
Sinoatrial node dysfunct	42781	-0.00923	0.0206
Subdural hemorrhage	4321	0.03408	0.0004
Stricture of artery	4471	0.00238	0.6534
Paralytic ileus	5601	0.10245	<.0001
Convulsions NEC	78039	0.10277	<.0001
Gangrene	7854	0.05466	<.0001
Cachexia	7994	0.14375	<.0001
Candidal esophagitis	11284	0.1985	<.0001
Sarcoidosis	135	0.0624	<.0001
Malignant neopl rectum	1541	0.1335	<.0001
Mal neo liver, primary	1550	0.12225	<.0001
Mal neo upper lobe lung	1623	0.08088	<.0001

ICD-9 Description	ICD-9 Code	Coefficient	P-value
Mal neo bronch/lung NOS	1629	0.13617	<.0001
Malign neopl prostate	185	-0.03133	<.0001
Malig neo bladder NOS	1889	0.10792	<.0001
Malig neopl kidney	1890	0.02548	0.0004
Malign neopl thyroid	193	-0.04837	0.0087
Secondary malig neo lung	1970	0.17282	<.0001
Second malig neo liver	1977	0.38071	<.0001
Secondary malig neo bone	1985	0.29043	<.0001
Malignant neoplasm NOS	1991	0.13518	<.0001
Oth lymph unsp xtrndrl org	20280	0.14363	<.0001
Mult mye w/o achv rmson	20300	0.19204	<.0001
Ch lym leuk wo achv rmsn	20410	0.25565	<.0001
Essntial thrombocythemia	23871	0.10421	<.0001
Low grde myelody syn les	23872	0.14376	<.0001
Myelodysplastic synd NOS	23875	0.17806	<.0001
DMII wo cmp nt st uncntr	25000	0.11986	<.0001
DMII wo cmp uncntrld	25002	0.02111	<.0001
DMII keto nt st uncntrld	25010	0.03729	<.0001
DMII ketoacd uncontrold	25012	0.13424	<.0001
DMI ketoacd uncontrold	25013	0.25355	<.0001
DMII hprosmrlr uncontrold	25022	0.12376	<.0001
DMII renl nt st uncntrld	25040	0.0746	<.0001
DMI renl nt st uncntrld	25041	0.04644	<.0001
DMII ophth nt st uncntrl	25050	0.00743	0.0064
DMI ophth uncntrld	25053	0.05823	<.0001
DMII neuro nt st uncntrl	25060	0.05824	<.0001
DMI neuro nt st uncntrld	25061	0.04909	<.0001
DMII neuro uncntrld	25062	0.07612	<.0001
DMI neuro uncntrld	25063	0.13715	<.0001
DMII circ nt st uncntrld	25070	-0.04017	<.0001
DMI circ nt st uncntrld	25071	-0.05298	<.0001
DMII circ uncntrld	25072	-0.02251	<.0001
DMII oth nt st uncntrld	25080	0.08205	<.0001
DMI oth nt st uncntrld	25081	0.02286	0.0002
DMII oth uncntrld	25082	0.03781	<.0001
DMI oth uncntrld	25083	0.00729	0.3939
Glucocorticoid deficient	25541	0.17576	<.0001
Oth severe malnutrition	262	0.0382	<.0001
Dis urea cycle metabol	2706	0.06036	0.0002
Amyloidosis NEC	27739	0.15827	<.0001
Metabolism disorder NEC	27789	0.21983	<.0001
Morbid obesity	27801	0.07927	<.0001

ICD-9 Description	ICD-9 Code	Coefficient	P-value
Obesity hypovent synd	27803	-0.05432	<.0001
Sickle cell disease NOS	28260	0.71791	<.0001
Antin chemo indcd pancyt	28411	0.10449	0.0005
Other pancytopenia	28419	0.1945	<.0001
Neutropenia NOS	28800	0.16551	<.0001
Drug induced neutropenia	28803	0.14431	<.0001
Prim hypercoagulable st	28981	0.18562	<.0001
Senile dementia uncomp	2900	-0.02563	0.0001
Senile delusion	29020	-0.11382	<.0001
Vascular dementia,uncomp	29040	-0.00174	0.8249
Drug withdrawal	2920	0.26748	<.0001
Dementia w/o behav dist	29410	0.01212	0.0613
Dementia w behavior dist	29411	-0.02334	0.0177
Demen NOS w/o behv dstrb	29420	0.04516	<.0001
Mental disor NEC oth dis	2948	0.04058	<.0001
Schizophrenia NOS-unspec	29590	0.15532	<.0001
Depress psychosis-unspec	29620	0.17524	<.0001
Recurr depr psychos-unsp	29630	0.08526	<.0001
Recur depr psych-severe	29633	0.07789	<.0001
Bipolar disorder NOS	29680	0.19198	<.0001
Bipolar disorder NEC	29689	0.08524	<.0001
Episodic mood disord NOS	29690	0.07786	<.0001
Alcoh dep NEC/NOS-unspec	30390	0.16788	<.0001
Alcoh dep NEC/NOS-remiss	30393	0.07322	<.0001
Opioid dependence-unspec	30400	0.25245	<.0001
Opioid dependence-contin	30401	0.18003	<.0001
Drug depend NOS-unspec	30490	0.27902	<.0001
Cereb degeneration NOS	3319	0.08582	<.0001
Grand mal status	3453	0.01548	0.1722
Psymotr epil w/o int epi	34540	-0.08114	<.0001
Anoxic brain damage	3481	-0.03408	0.0008
Idio periph neurpthy NOS	3569	0.09859	<.0001
Neuropathy in diabetes	3572	0.04133	<.0001
Critical illness myopathy	35981	-0.09196	<.0001
Prolif diab retinopathy	36202	-0.08631	<.0001
Mod nonprolf db retinoph	36205	-0.07697	<.0001
Diabetic macular edema	36207	-0.0601	<.0001
Hyp ht dis NOS w ht fail	40291	0.03839	<.0001
Pulm embol/infarct NEC	41519	0.13237	<.0001
Prim pulm hypertension	4160	-0.01251	0.0316
Chr pulmon heart dis NEC	4168	0.15189	<.0001
Prim cardiomyopathy NEC	4254	0.16394	<.0001

ICD-9 Description	ICD-9 Code	Coefficient	P-value
Crbl emblsm w infrct	43411	0.01754	0.0772
Crbl art ocl NOS w infrc	43491	0.07113	<.0001
Aortic atherosclerosis	4400	0.09852	<.0001
Athscl extrm ntv art NOS	44020	0.00141	0.6632
Ath ext ntv at w claudct	44021	0.04379	<.0001
Ath ext ntv at w rst pn	44022	0.09607	<.0001
Ath ext ntv art ulcrtion	44023	0.02268	<.0001
Dsct of thoracic aorta	44101	0.23712	<.0001
Lower extremity aneurysm	4423	0.10898	<.0001
Periph vascular dis NEC	44389	0.01881	0.0012
Periph vascular dis NOS	4439	0.09731	<.0001
Deep phlebitis-leg NEC	45119	0.00269	0.7906
Oth inf vena cava thromb	4532	0.2153	<.0001
Ac DVT/emb prox low ext	45341	0.12676	<.0001
Ch DVT/embl low ext NOS	45350	0.12558	<.0001
Ch DVT/embl prox low ext	45351	0.09937	<.0001
Ch emblsm subclav veins	45375	0.17741	<.0001
Ac DVT/embl up ext	45382	0.08862	<.0001
Ac emblsm axillary veins	45384	0.10835	<.0001
Ac embl internl jug vein	45386	0.16307	<.0001
Ac embl thorac vein NEC	45387	0.13445	<.0001
Esoph varice oth dis NOS	45621	0.19764	<.0001
Obs chr bronc w(ac) exac	49121	0.16393	<.0001
Obs chr bronc w ac bronc	49122	0.11419	<.0001
Emphysema NEC	4928	0.05787	<.0001
Chronic obst asthma NOS	49320	0.10527	<.0001
Ch obst asth w (ac) exac	49322	0.10999	<.0001
Bronchiectas w/o ac exac	4940	0.06175	<.0001
Chr airway obstruct NEC	496	0.1908	<.0001
Food/vomit pneumonitis	5070	0.05726	<.0001
Postinflam pulm fibrosis	515	0.11769	<.0001
Lung involv in oth dis	5178	0.17403	<.0001
Ac resp flr fol trma/srg	51851	-0.04255	0.0003
Ot pul insuf fol trm/srg	51852	-0.0827	0.0003
Other pulmonary insuff	51882	0.13098	<.0001
Chronic respiratory fail	51883	0.0293	<.0001
Acute & chronc resp fail	51884	0.02507	<.0001
Gastrostomy comp - mech	53642	0.10042	<.0001
Regional enteritis NOS	5559	0.17154	<.0001
Ulceratve colitis unspcf	5569	0.06821	<.0001
Chr vasc insuff intest	5571	0.15765	<.0001
Fecal impaction	56032	0.09744	<.0001

ICD-9 Description	ICD-9 Code	Coefficient	P-value
Intestinal obstruct NOS	5609	0.10671	<.0001
Alcohol cirrhosis liver	5712	0.05621	<.0001
Cirrhosis of liver NOS	5715	0.20344	<.0001
Hepatic encephalopathy	5722	0.17945	<.0001
Portal hypertension	5723	0.20086	<.0001
Oth sequela, chr liv dis	5728	0.14523	<.0001
Chronic pancreatitis	5771	0.38153	<.0001
Pressure ulcer, low back	70703	0.0362	<.0001
Pressure ulcer, hip	70704	0.09173	<.0001
Pressure ulcer, buttock	70705	0.00396	0.4043
Ulcer of lower limb NOS	70710	0.01138	0.0098
Ulcer other part of foot	70715	0.04066	<.0001
Ulcer oth part low limb	70719	0.03358	<.0001
Chronic skin ulcer NEC	7078	0.07843	<.0001
Syst lupus erythematosus	7100	0.24781	<.0001
Systemic sclerosis	7101	0.12899	<.0001
Pyogen arthritis-unspec	71100	0.03922	0.0151
Pyogen arthritis-l/leg	71106	0.11218	<.0001
Rheumatoid arthritis	7140	0.10921	<.0001
Inflamm polyarthrop NOS	7149	0.02641	0.1369
Sacroiliitis NEC	7202	0.16649	<.0001
Ac osteomyelitis-unspec	73000	-0.04005	0.0005
Ac osteomyelitis-ankle	73007	-0.03799	<.0001
Ac osteomyelitis NEC	73008	-0.01851	0.102
Osteomyelitis NOS-hand	73024	0.05835	0.0001
Osteomyelitis NOS-ankle	73027	-0.03107	<.0001
Path fx vertebrae	73313	0.1329	<.0001
Aseptic necrosis femur	73342	0.20291	<.0001
Asept necrosis bone NEC	73349	0.17431	<.0001
Coma	78001	0.02143	0.1083
Fracture of pubis-closed	8082	0.06248	<.0001
Pelvic fracture NOS-clos	8088	-0.01048	0.4819
Fx femur intrcaps NEC-cl	82009	0.03652	0.0079
Fx neck of femur NOS-cl	8208	-0.02685	<.0001
Fx femur NOS-closed	82100	-0.05632	<.0001
Amput below knee, unilat	8970	-0.10393	<.0001
Amputat bk, unilat-compl	8971	-0.10582	<.0001
Amput above knee, unilat	8972	-0.08573	<.0001
Amputat leg, unilat NOS	8974	-0.077	<.0001
React-indwell urin cath	99664	0.15093	<.0001
Compl heart transplant	99683	0.02305	0.3552
Asymp hiv infectn status	V08	0.37403	<.0001

ICD-9 Description	ICD-9 Code	Coefficient	P-value
Heart transplant status	V421	0.26702	<.0001
Liver transplant status	V427	0.16234	<.0001
Trnspl status-pancreas	V4283	0.14978	<.0001
Gastrostomy status	V441	0.02184	0.0173
Ileostomy status	V442	0.12312	<.0001
Colostomy status	V443	0.13378	<.0001
Urinostomy status NEC	V446	0.33981	<.0001
Respirator depend status	V4611	-0.02597	0.001
Status amput othr toe(s)	V4972	0.031	<.0001
Status amput below knee	V4975	0.02473	<.0001
Status amput above knee	V4976	0.01774	0.0036
Atten to gastrostomy	V551	-0.03053	0.0012
Long-term use of insulin	V5867	0.12534	<.0001
BMI 40.0-44.9, adult	V8541	0.03116	<.0001
	miss_comorb	0.73799	<.0001

Adjustments for race, ethnicity, and sociodemographic status

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

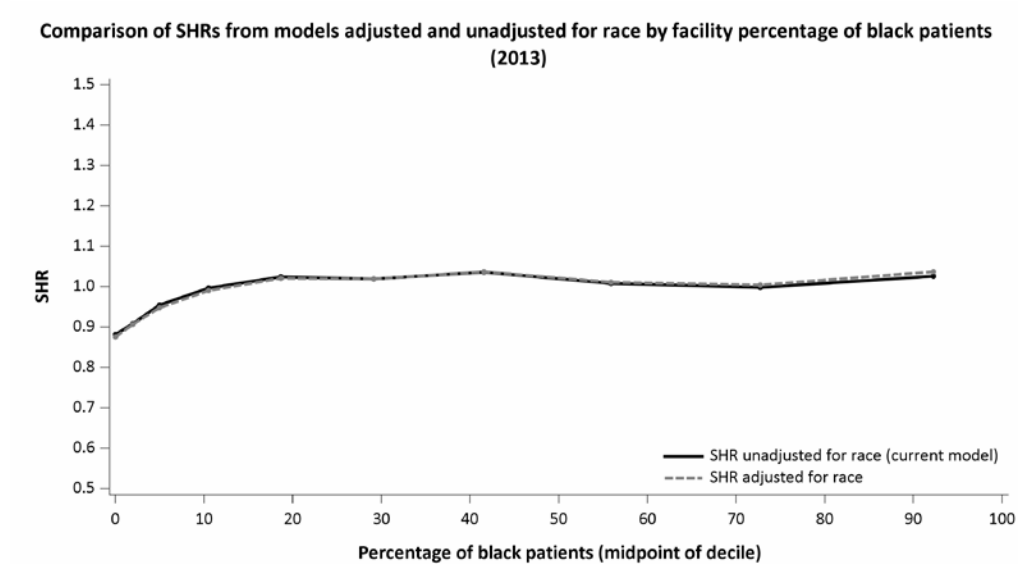


Figure 2. Comparison of SHRs adjusted and not adjusted for Hispanic ethnicity by facility percentage of Hispanic patients (deciles), 2013

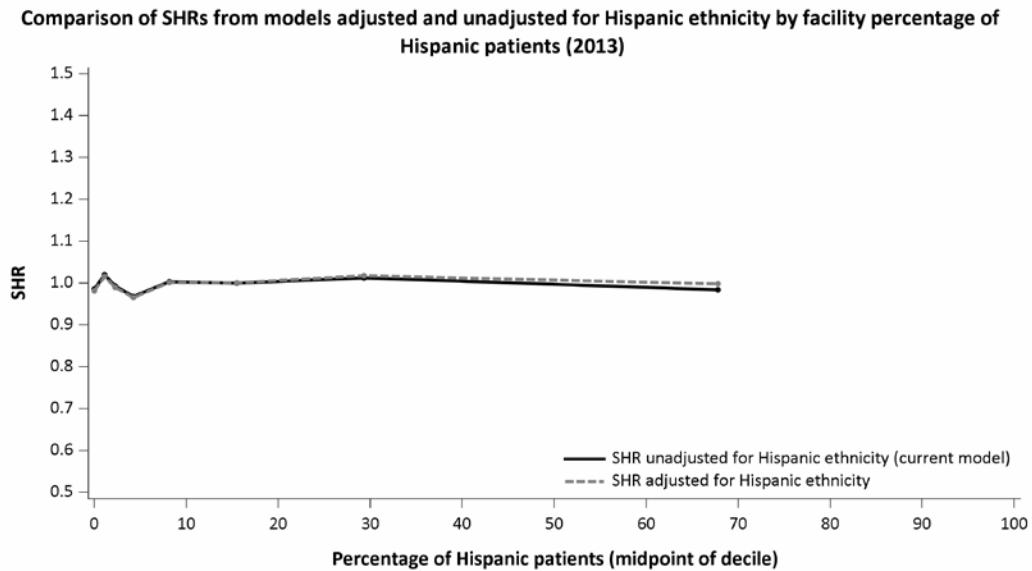
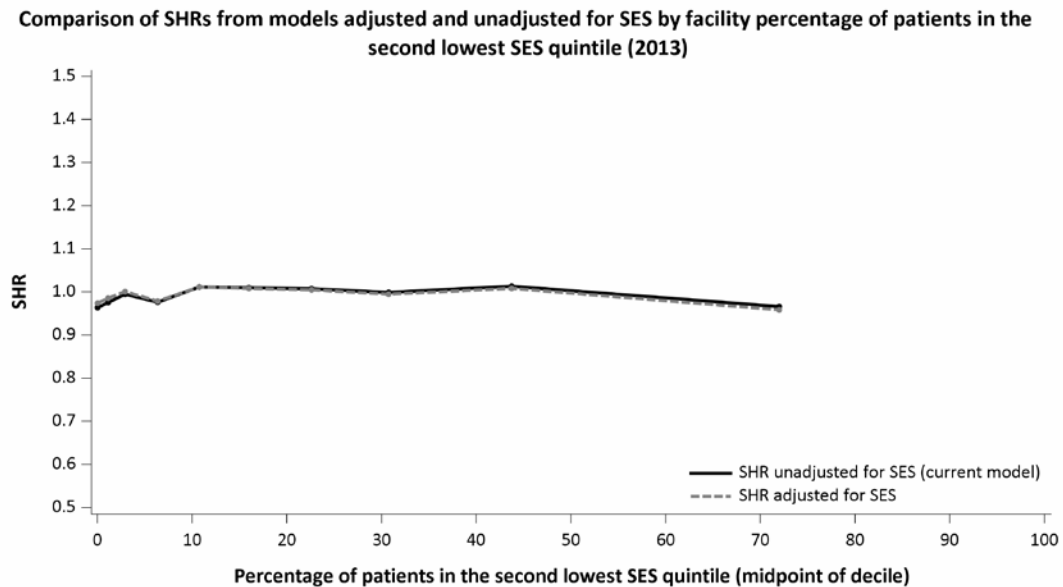


Figure 3. Comparison of SHRs adjusted and not adjusted for SES by facility percentage of patients in the second lowest SES quintile (deciles), 2013*



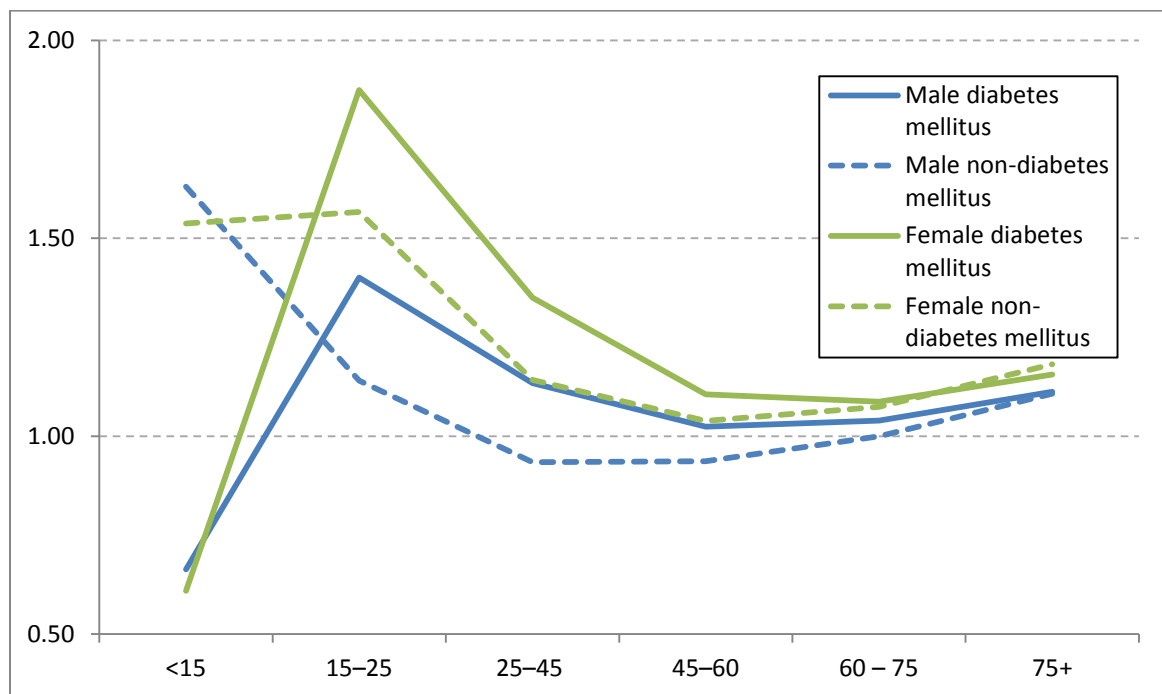
* SES was included in the adjusted SHR model as quintiles. SES was defined for each patient as the median household income for the patient's zip code. The second lowest quintile included median household incomes between \$33,907 and \$41,918.

Adjustment for sex

Table 2a above presents the manner in which the SHR adjusts for sex, given current judgment that physiology accounts for some, if not a substantial part, of observed differences in hospitalization by sex. The main adjustment reflects the observation that, adjusting for age and a set of comorbidities, females are more likely to be hospitalized. The interaction terms for age and sex in the model indicate that the effect of sex depends substantially on patient age. In particular, females in child-bearing years are more likely to be hospitalized than very young females and old females. Therefore, women in the 15-45 age range face a greater risk of experiencing an admission, as compared to men of the same age with similar risk profiles. This does not appear to be a consequence of facility performance, however, because the disparity is not generally applicable to women, but only to a limited age group. It is therefore important to risk adjust for sex to ensure that women in facilities with larger numbers of women aged 15 to 45 are not inappropriately disadvantaged in terms of access to care.

Figure 4 shows the interaction of age and sex in the SHR model, for patients diagnosed with and without diabetes. The figure makes clear that for both male and female patients, independent of diagnoses of diabetes, hospitalization is strongly associated with young age. Further, the male-female difference is concentrated in the younger age categories. Beyond age 45, where the hospitalization rates are generally quite low, there is very little difference between males and females. The figure demonstrates that high hospitalization rates for females reflects utilization by younger females, suggesting a physiologic effect rather than a systematic difference in care by sex.

Figure 4. Relative effects of coefficients related to sex in the 2013 SHR model



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

Two-way interactions were examined and selected for the final model based on both the magnitude and statistical significance of the estimates.

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

The C-statistic for a recurrent event model measures the concordance between the observed rate of recurrent events and the model-based rate. The estimate of the c-statistic for the SHR is 0.65.

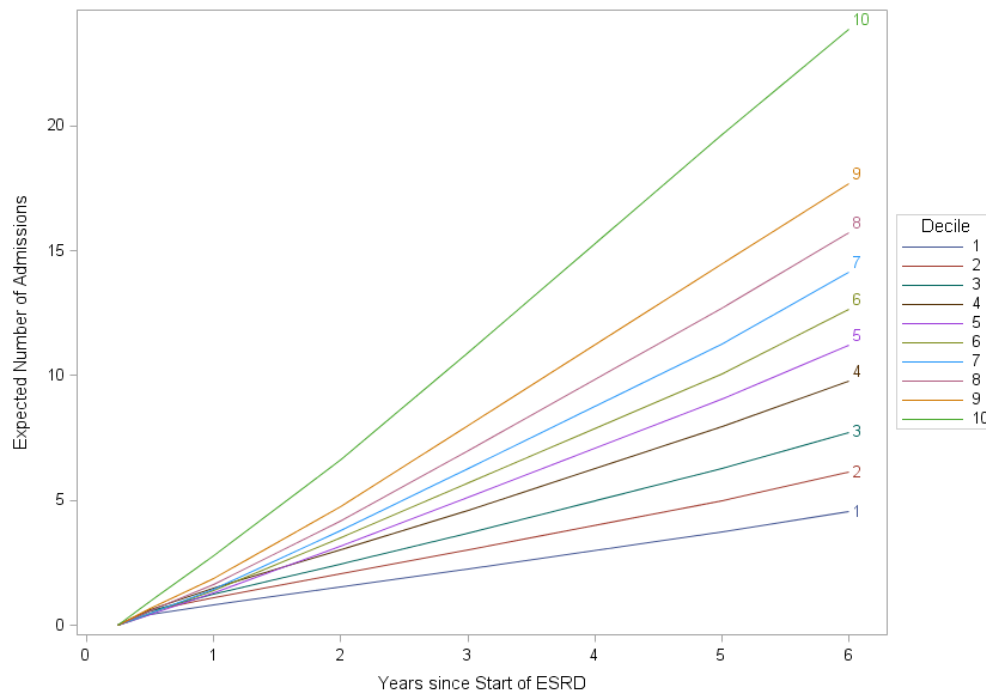
2b4.7. Statistical Risk Model Calibration Statistics (e.g., Hosmer-Lemeshow statistic)

N/A

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

Decile plots showing piecewise linear estimates of the cumulative rates by years since start of ESRD are plotted in Figure 5.

Figure 5. Decile Plot for SHR Admissions (2013 data).



Martingale residual plots were also examined (Figures 6-8).

Figure 6. Martingale Residuals by Age of Patient with LOESS Curve (2013 data).

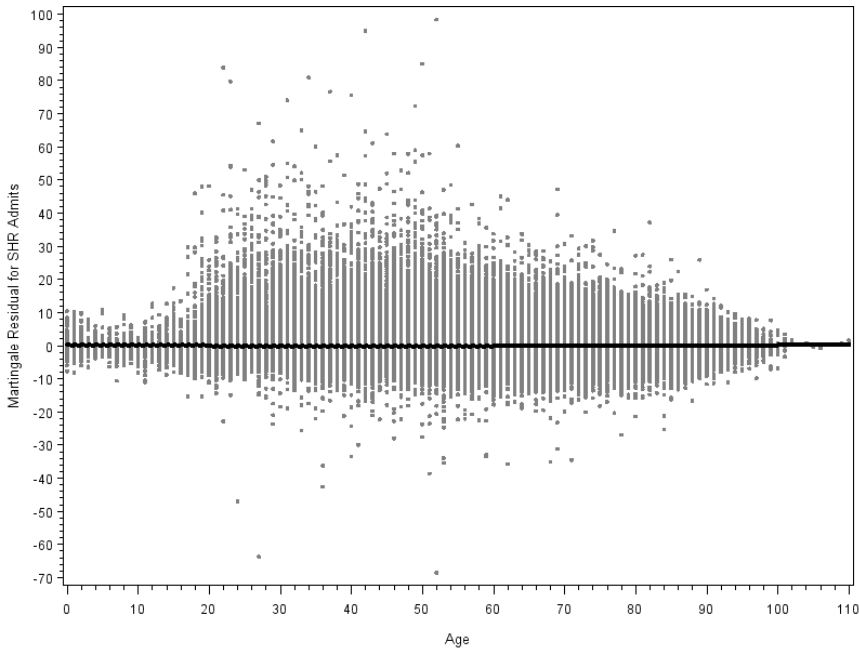


Figure 7. Martingale Residuals by BMI of Patient with LOESS Curve (2013 data).

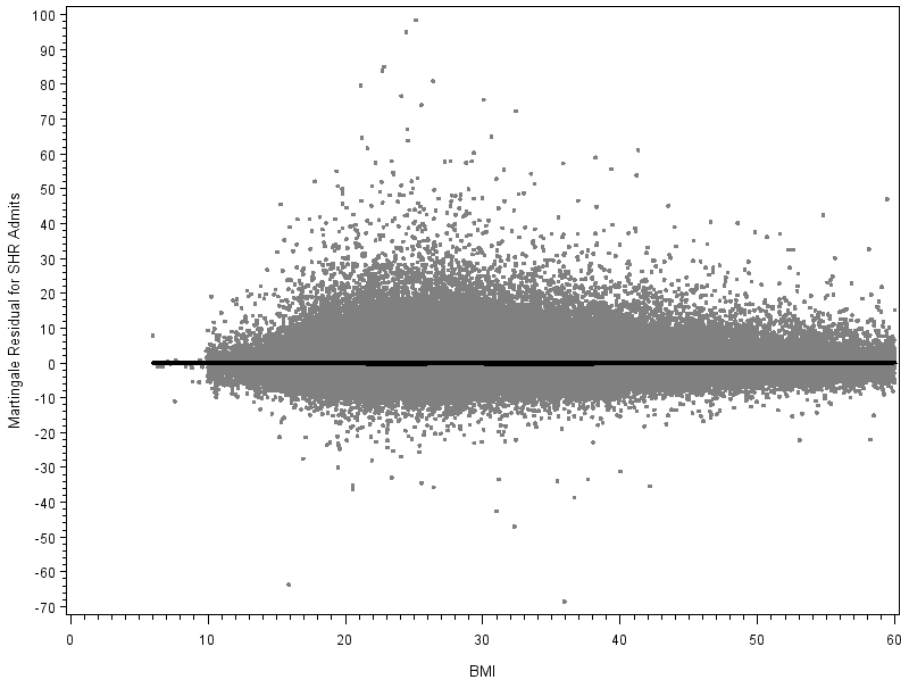
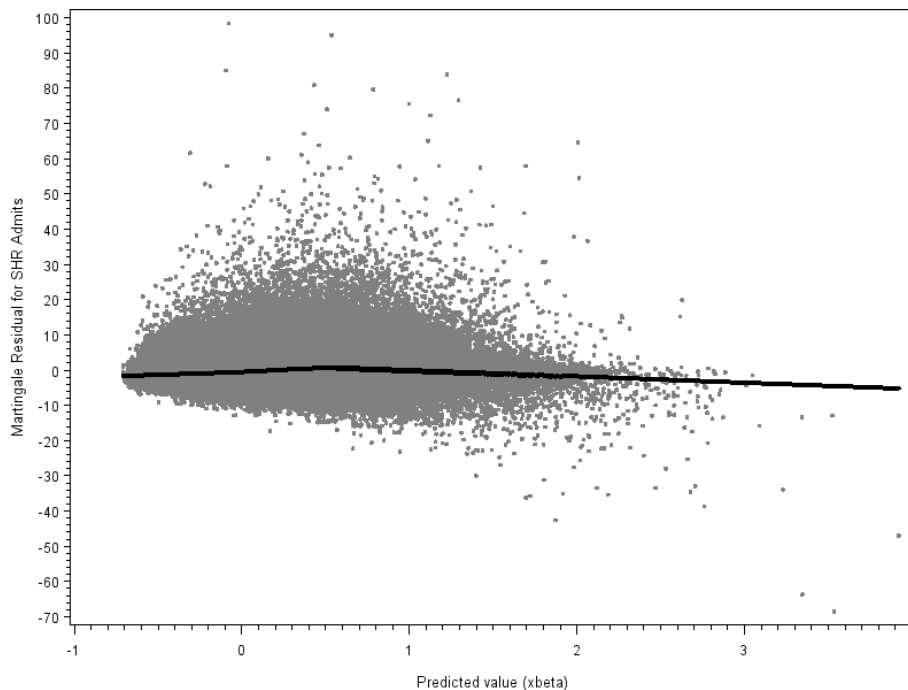


Figure 8. Martingale Residuals by Predicted Value of Patient with LOESS Curve (2013 data).



2b4.9. Results of Risk stratification Analysis

N/A

2b4.10. Interpretation

The decile 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 lower hospitalization rates). The absolute differences between the groups is also large, with patients predicted to have the highest hospitalization rates (line 10) having 3 times higher hospitalization rates than those predicted to have the lowest rates (line 1).

The Martingale residual plots also did not indicate problems with the model fit. There was no pattern in the residuals that suggested lack of fit in any of the variables considered. In the LOESS plots attached, the LOESS curve for the mean of the residuals is flat indicating that there is no problem with the fit for each of the variables considered. The adjustment variables are highly predictive of the hospital admissions, and model extensions to examine interactions suggest a good overall fit.

2b4.11. Optional Additional Testing for Risk Adjustment

N/A

2b5—Identification of statistically significant and clinically meaningful differences

2b5.1. Method for determining

To adjust for over-dispersion of the data, we compute the p-value for our estimates using the empirical null distribution, a robust approach that takes account of the natural random variation among facilities that is not accounted for in the model (Efron, 2004; Kalbfleisch and Wolfe, 2013). Our algorithm consists of the following concrete steps. First, we fit an over-dispersed Poisson model (e.g., SAS PROC GENMOD with link=log, dist=poisson and scale=dscale) for the number of hospital admissions

$$\log(E[n_{ik}]) = \log(E_{ik}) + \theta_k,$$

where n_{ik} is the observed number of events for patient i in facility k , E_{ik} is the expected number of events for patient i in facility k and θ_k is the facility-specific intercept. Here, i ranges over the number of patients N_k who are treated in the k th facility. The natural log of the SHR for the k th facility is then given by the corresponding estimate of θ_k . The standard error of θ_k is obtained from the robust estimate of variance arising from the overdispersed Poisson model.

Second, we obtain a z-score for each facility by dividing the natural log of its SHR by the standard error from the general linear model described above. These z-scores are then grouped into quartiles based on the number of patient years at risk for Medicare patients in each facility. Finally, using robust estimates of location and scale based on the normal curve fitted to the center of the z-scores for the SHR, we derive the mean and variance of a normal empirical null distribution for each quartile. This empirical null distribution is then used to calculate the p-value for a facility's SHR.

2b5.2. Statistical Results

Table 3. Number and percentage of facilities by classification of SHR, 2013. Categories stratified by facility size.

Number of patients	Better than expected	As expected	Worse than expected
< 51	0.26% (15)	31.86% (1,866)	1.47% (86)
51 - 87	0.39% (23)	31.71% (1,857)	1.79% (105)
> 87	0.43% (25)	30.46% (1,784)	1.64% (96)

2b5.3. Interpretation

Without empirical null methods, a large number of facilities will be flagged, including many larger facilities with a relatively small difference between the rates of hospitalization. In contrast, the methods based on the empirical null make appropriate adjustments for overdispersion. Using this method, facilities are flagged if they have outcomes that are extreme when compared to the variation in outcomes for other facilities of a similar size. Overall, most facilities are flagged as expected (94.03%), while approximately 1% are better than expected, and approximately 5% are flagged as 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

N/A

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 that are eligible for the measure, and have at least 5 patient years at risk. For the most recent DFC report, that was 5,784 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

Hospitalization rates have decreased over time as evidenced by the coefficients for calendar year from the SHR model. The hospitalization rate for 2011 decreased by 3% compared to 2010 (p-value <0.0001). Subsequent years had a larger decrease in the hospitalization rate compared to 2010 at 12.7% lower for 2012 and about 16.2% lower for 2013 (p-value<0.0001 for both).

SHR Calendar Year Model Coefficients, 2010-2013

2011: Coefficient = -0.03, P-value = <0.0001

2012: Coefficient = -0.127, P-value = <0.0001

2013: Coefficient = -0.162, 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

#0369: Standardized Mortality 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

These measures are not completely harmonized. Each measure assesses different outcomes as reflected in certain differences across the measure specifications. SHR, SMR 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. SHR and SMR adjust for all the same comorbidity risk factors, a similar set of patient characteristics, and use fixed effects in their modeling approach.

The differences between SHR, SMR and SRR reflect adjustment for factors specific to the outcome of each respective measure. Both SHR and SMR adjust for a set of prevalent comorbidities (observed in a prior year), however the complete set of comorbidities differs for SRR. SRR excludes planned readmissions; and adjusts 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 SHR or SMR.

SHR adjusts for sex to account for sex-age specific effects associated with higher hospitalization. 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 this advisory role, the primary duty of the TEP was to review any existing measures in terms of comorbidities included as adjusters, and determine if there was sufficient evidence to support the inclusion of specific proposed comorbidities as measure adjusters, and relatedly, suggest measure specifications,.

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

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Outcomes Monitoring Program, Dialysis Clinic Inc.
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Chronic Disease Research Group
Minneapolis, MN

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American Society of Nephrology
Lexington, MA

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Assistant Professor of Medicine
Chapel Hill, NC

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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 SHR for these facilities. Within each facility, select at random and with replacement B bootstrap samples. Our numerical experiments reveal that $B=100$ is sufficient. 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 SHR_i and repeat the process B (say, 100) times. Thus, for the i th facility, we have bootstrapped SHRs 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 SHR, 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 SHR and

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

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

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

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