



TO: Joel Andress, PhD  
Centers for Medicare and Medicaid Services  
  
University of Michigan Epidemiology and Cost Center  
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DA: February 24, 2016

RE: Public Comment on Standardized Mortality Ratio (SMR) and Standardized Hospitalization Ratio (SHR)

Kidney Care Partners (KCP) is a coalition of members of the kidney care community that includes the full spectrum of stakeholders related to dialysis care – patient advocates, health care professionals, dialysis providers, researchers, and manufacturers and suppliers – organized to advance policies that improve the quality of care for individuals with chronic kidney disease and end stage renal disease (ESRD). We appreciate the opportunity to comment on the draft specifications for the SMR and SHR developed under a CMS contract by the University of Michigan Kidney Epidemiology and Cost Center and posted on February 8, 2016.

Because the measures share much in common, we have organized the comments in five areas; when a comment pertains only to one of the measures, we specifically note this. The six areas are:

1. Specifications
2. Co-Morbidities
3. Risk Model Fit
4. Reliability and Validity Testing
5. Ratio vs. Rate Measures

## 1. SPECIFICATIONS

KCP offers several comments on the specifications

- **SMR Measurement Period.** The SMR specifications for the time period state “at least one year.” As a principle, KCP believes specifications should be unambiguous – i.e., the construction is imprecise. We believe the time period should be an exact period, and we further believe the 1-year period is inappropriate based on the testing data. We recommend, at minimum, a 4-year period.

CMS’s reliability testing for the 1-year SMR yielded IURs of 0.26-0.32 for each of 2010, 2011, 2012, and 2013 – a low degree of reliability, where only about 30% of the variation in a score can be attributed to between-facility differences. Using the 4-year SMR yielded an IUR of 0.66 (2009-2012) – i.e., about 60% of the variation can be attributed to between-facility differences; for 2010-2013 data, the IUR was only 0.59. We further note

a reliability statistic of 0.70 is often considered as “good” reliability,<sup>1</sup> though the characterization also depends on the analytic method. The overall reliability, even for the 4-year SMR, falls short in this regard.

Not surprisingly, reliability depends on facility size. Even with the 4-year SMR, the testing results still indicate poor reliability for small (IUR=0.30) and medium (IUR=0.45) facilities – i.e., only large facilities have a reasonable IUR of 0.73 for 2010-2013 data. Given these results, we also believe it is incumbent on CMS to address the lack of reliability and use an adjuster or otherwise account the poor reliability in small and medium facilities before the measure is implemented.

- **SHR Measurement Period.** The SHR specifications for the time period also state “at least one year.” Again, as a principle, KCP believes specifications should be unambiguous. We believe the time period should be an exact period. Further, based on the results from the reliability testing, we have significant concerns about the reliability of the 1-year SHR for small and medium facilities (IUR range of 0.46-0.65, depending on the year. Given there are a significant number of facilities that have fewer than 87 patients, KCP requests that CMS reanalyze the data and set the time period so the reliability/IUR is satisfactory, even for small facilities.
- **SMR and SHR Denominator.** KCP supports limiting the denominator to Medicare patients. As you know, KCP has long advocated that the measures should account for more current co-morbidity data, and we understand and support the trade-off to now limit the denominator population due to claims data availability.
- **SMR Exclusion for Incident Hospice Patients.** The NQF Measure Applications Partnership (MAP) recently did not support the SMR in part because the measure did not exclude patients who are already in hospice when they initiate dialysis. During the MAP deliberations, it was noted that occasionally incident patients begin dialysis treatments while in hospice, but then choose to discontinue them after a period of time. KCP supports MAP’s recommendation that patients who initiate dialysis while also in hospice be excluded from the SMR. As currently constructed, such patients are attributed to the facility providing the dialysis.

## 2. CO-MORBIDITIES

We strongly support the use of prevalent co-morbidities in the risk models for the SMR and SHR, and commend CMS for moving to incorporate prevalent co-morbidities in the proposed specifications – an approach for which KCP has long advocated. We also encourage CMS to review co-morbidities as they relate to the ESRD population under the age of 18 years, since these measures include all ESRD patients. We comment separately on the approaches for incident vs. prevalent co-morbidities.

- **Incident Co-morbidities.** Incident co-morbidities will continue to be derived from the 2728, but the new model proposes adjustments for each incident comorbidity separately instead of using a “comorbidity index.” Diabetes also is proposed as a single comorbidity, whereas before the model used four separate indicators. KCP supports treating each incident comorbidity separately, including diabetes. As we have noted before, however, we continue to be concerned about the validity of the 2728 as a data source. We urge CMS to work with the community to assess this matter.

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<sup>1</sup> Adams, JL. The Reliability of Provider Profiling: A Tutorial. Santa Monica, California:RAND Corporation. TR-653-NCQA, 2009.

- **Prevalent Co-morbidities.** KCP supports the inclusion of prevalent co-morbidities derived from Medicare claims data, but the review time does not permit us to comment specifically on the 555 co-morbidities originally considered, nor the 210 ultimately included. While we may in the future (e.g., during NQF review) comment on specific items, we note the face validity of some co-morbidities that have been included in the model is puzzling (e.g., “urinostomy status not elsewhere classified [NEC]”, “sacroiliitis NEC”). One approach might be to assess posterior probability. In sum, while we appreciate the details provided in the TEP report, we believe there are anomalies among the 210 co-morbidities and suggest a transparent process to refine the list.

Further, in reviewing the approach used to identify appropriate prevalent co-morbidities, the TEP report indicates an initial assessment was applied to the ESRD Hierarchical Comorbidity Conditions (HCCs) with a prevalence of at least 0.1% in the patient population in order to identify those with a statistically significant relationship to mortality and/or hospitalization ( $p < 0.05$ ). However, we note that many of the co-morbidities included in the final model appear to have p-values significantly greater than 0.05 (e.g., paralytic ileus [ $p = 0.5007$ ], episodic mood disorder NOS [ $p = 0.8254$ ]) and so are puzzled as to the rationale for their inclusion. We seek clarification on this apparent discrepancy between the described approach to co-morbidity selection and the end-product.

- **Determination of Co-morbidities.** The determination that a prevalent co-morbidity exists requires at least two outpatient claims or one inpatient claim. No TEP justification or empirical analyses were offered to justify this algorithm. KCP requests the underlying rationale for the approach.

### 3. RISK MODEL

KCP is pleased the model incorporates prevalent co-morbidities, but we have a few concerns related to the model’s details.

- **Model Fit.** Testing yields a c-statistic for the SMR of 0.724, and a c-statistic for the SHR of 0.65. We are concerned the model will not adequately discriminate performance – particularly that smaller units, including pediatric units, might look worse than reality. We believe a minimum c-statistic of 0.8 is a more appropriate indicator of the model’s goodness of fit and validity to represent meaningful differences among facilities, and seek an ongoing commitment from CMS to improve the model.
- **Nursing Home Status:** The Measure Information Form (MIF) indicates patient characteristics included in the stage 1 model as covariates include “Nursing home status in *previous* year.” It is unclear to us if this means that patients moving into a nursing home for the first time *during* the measurement year would not be adjusted for “nursing home status”. KCP seeks clarification as to whether the look-back is *one year prior to the given event* (inclusive of the data year) or if this verbiage means the look-back is *in the previous calendar year* (not inclusive of the data year); we recommend the current reporting year be included, not just the previous one.
- **Age:** The age groups for the SMR (n=3) differ from those for the SHR (n=6). No TEP justification or empirical analyses were offered to justify this difference. KCP requests the underlying rationale and empirical justification for the approach, given the general principle that specifications should be harmonized when appropriate and possible.
- **Duration of ESRD.** Similarly, the number of groups for ESRD duration for the SMR (n=4) differs from that for the SHR (n=6). No TEP justification or empirical analyses

were offered to justify this difference. KCP requests the underlying rationale for the approach and empirical justification, given the general principle that specifications should be harmonized when appropriate and possible.

#### 4. RELIABILITY AND VALIDITY

As we noted under Item 1, Specifications, we have significant concerns about the reliability of both the SMR and SHR and make recommendations on the specifications.

We noted the Spearman's correlation coefficients for SHR-SMR ranged from 0.27-0.30; SHR-SRR = 0.48-0.54; SHR-AVF = -0.15 to -0.12; SHR-catheter = 0.16-0.21; SHR- Kt/V $\geq$ 1.2 = -0.13 to -0.10. Again, these correlations are directionally as expected. However, KCP believes the Measure Justification Form (MJF) overstates these correlations, concluding, "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." By convention, Spearman's rho of 0-0.19 appears to be considered "very weak" and must be 0.60-0.79 to be considered "strong."<sup>2</sup> We request the results be more accurately characterized, as they were for SMR – i.e., that the correlations were directionally as expected.

Additionally, for the facility minimum data requirements, the MJF notes at least 3 expected deaths must occur for inclusion in the SMR calculations. No TEP justification or empirical analyses were offered to justify this threshold. KCP requests information on the underlying analysis – e.g., how many clinics were excluded using this approach and what is the impact on scoring because of the exclusion? Similarly, for SHR the minimum requirement is 5 patient-years at risk. KCP notes the STrR uses 10 patient-years at risk. No TEP justification or empirical analyses are offered to justify this difference. KCP again requests the underlying rationale for the approach and empirical justification, given the general principle that specifications should be harmonized when appropriate and possible.

#### 5. RATIO VS. RATE MEASURES

The proposed specifications for the SMR and SHR indicate the measures can be calculated as rates. KCP prefers normalized rates or year-over-year improvement in rates instead of a standardized ratio. We believe comprehension, transparency, and utility to all stakeholders is superior with a scientifically valid *rate* methodology. We note that MAP also did not support the SMR because, in addition to the lack of a hospice exclusion, as previously noted, MAP felt "mortality rates would be more meaningful to consumers and actionable for facilities."

KCP again thanks you for the opportunity to comment on this important work. If you have any questions, please do not hesitate to contact Lisa McGonigal, MD, MPH (lmcgon@msn.com or 203.298.0567).

Sincerely,

AbbVie  
Akebia  
American Kidney Fund  
American Nephrology Nurses Association  
American Renal Associates  
American Society of Nephrology  
American Society of Pediatric Nephrology

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<sup>2</sup> Stats Tutor, *Spearman's Correlation*. Available at [www.statstutor.ac.uk](http://www.statstutor.ac.uk). Last accessed February 2016.

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