KIDNEY CARE
PARTNERS

TO: Joel Andress, PhD
        Centers for Medicare and Medicaid Services

        University of Michigan Epidemiology and Cost Center
        dialysisdata@umich.edu

DA: March 3, 2016

RE: Public Comment on Standardized Transfusion Ratio (STrR)

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 Standardized Transfusion Ratio (STrR) developed under a CMS contract by the University of Michigan Kidney Epidemiology and Cost Center and posted on February 16, 2016.

We have organized the comments in seven areas:

1. Specifications

2. Co-morbidities

3. Failure of the risk model to account for hospital-or physician-related factors

4. Risk model fit

5. Reliability and validity

6. Ratio vs. rate measures

7. Imprecision and inconsistencies in definitions across measures

1. SPECIFICATIONS
    KCP offers several comments on the STrR measure specifications.

- **Revised Transfusion Events Definition.** CMS has revised the measure specifications to more "conservatively" define transfusion events, such that all inpatient transfusion events must include, at a minimum, an appropriate ICD-9 Procedure Code or Value Code to be captured in the measure—inpatient transfusion events for claims that include only 038 or 039 revenue codes without an accompanying procedure or value code are excluded. The specifications also specify a maximum of one event per day and that an event not be defined by the number of units of blood transfused.

    KCP supports and appreciates the need to refine and tighten how transfusion events are counted and applauds CMS's intent in undertaking these revisions, but we do not believe the proposed solution is a valid representation of transfusion events. Importantly, there is no existing requirement that procedure or value codes be used,

which means valid transfusion claims that do not include these codes will be missed.

Current transfusion coding practices clearly vary by hospital,[1] and hospital coding practices are beyond dialysis facilities' sphere of control. For example, we are aware of hospitals that exclusively use revenue codes and do not use the procedure or value codes. In-patients at this type of hospital will appear to have no transfusion events assigned to the dialysis facility, whereas those at a hospital that uses the codes will have recorded events. Simply put, facilities within given catchment areas will be differentially affected by hospital coding variations, which clearly impact measure scoring. We are particularly concerned that the revisions, if implemented, will result in increased variability in performance across dialysis facilities wholly due to external factors and not performance. Facilities will appear to have "poor" performance because of higher than expected numbers of transfusions—and will expend time and resources to improve—when in fact the score is merely a reflection of coding practices.

KCP strongly supports the need to refine how transfusion events are defined, but believes the proposed specification changes result in a measure with significant threats to validity. We urge CMS to continue considering alternative models to define transfusion events. Alternatively, we suggest CMS consider revising hospital transfusion coding rules to require that the ICD-9/ICD-10 procedure and value codes necessary for the validity of the proposed methodology be universally included in claims.

- **Typographical Error.** The STrR specifications indicate the measure is "calculated as a rate, but also can be expressed as a ratio." We believe this is a typographical error, since the rest of the specifications present the measure as a ratio.

- **Minimum Patient Exclusion.** CMS indicates in the Measure Justification Form (MJF) that facilities with fewer than 10 patients are excluded from the STrR, and testing and performance analyses comport with this construct. However, we note the measure specifications per se do not specifically indicate this facility-level exclusion, and recommend the denominator statement be modified specifically in this regard.

2. CO-MORBIDITIES

KCP notes that while the SMR and SHR have been revised to incorporate prevalent co-morbidities into their risk models, the STrR has not been so revised; only incident co-morbidities, derived from the Medical Evidence Form (CMS 2728), are considered. We have several concerns and recommendations in this regard.

- **Incident Co-morbidities.** As in the past, information on patient co-morbidities will continue to be derived from the 2728 and thus reflect only those conditions present upon commencement of dialysis. As we have noted before, we continue to be concerned about the validity of the 2728 as a data source and urge CMS to work with the community to assess this matter.

Additionally, the updated SMR and SHR risk models adjust for each incident co-morbidity separately instead of using a "co-morbidity index" and approaches diabetes as a single co-morbidity rather than four separate indicators (currently on insulin, on oral medications, without medications, diabetic retinopathy). Again, the STrR has not been similarly revised. KCP has significant concerns about this failure to harmonize the

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[1] Weinhandl ED, Gilbertson DT, Collins AJ. Dialysis facility-level transfusion rates can be unreliable due to variability in hospital-level billing patterns for blood. Chronic Disease Research Group poster, ASN. 2014.

STrR with the SMR and SHR; CMS should align the STrR with the other measures so that each co-morbidity is examined separately (i.e., unbundled, as compared to the current measure) and diabetes is approached as a single co-morbidity (i.e., bundled, as compared to the current measure).

- **Prevalent Co-morbidities.** Again, we note the SMR and SHR have been revised to incorporate prevalent co-morbidities into their risk models, and KCP has commended CMS for this decision—an approach for which KCP has long advocated. The STrR risk model, however, has not been similarly revised. Prevalent co-morbidities also must be addressed in the STrR. We believe the failure to harmonize the STrR with the SMR and SHR or, at minimum, address prevalent co-morbidities and justify why they may differ from the SMR and SHR is a significant issue.

3. HOSPITAL- AND PHYSICIAN-RELATED FACTORS

We note that NQF reviewed but did not endorse the STrR in 2015, in part because the NQF Renal Standing Committee raised concerns about the measure reflecting the transfusion practices and behaviors at the hospital level and not for dialysis facilities. KCP concurred with this assessment, and noted because transfusions do not occur in dialysis facilities, it is difficult for facilities to influence whether a patient receives a transfusion—and facilities often do not even know if a patient has received a transfusion.

To address these concerns, KCP again suggests that CMS provide transfusion data directly to facilities on a quarterly basis by using DFR calculations and the six-month lagged data file; this would help facilities know when transfusions occur and give them the opportunity to try to determine the reason for the transfusions. In addition, we reiterate the measure could be improved by incorporating hospital- or physician-related factors into the risk model. Because physicians independently, or following hospital protocols, make decisions about whether or not to transfuse a specific patient, it is important to account for the variability these factors create.

4. RISK MODEL

KCP has a number of concerns related to the STrR risk model details—in particular, data presented on the model's goodness-of-fit.

- **Goodness-of-Fit Statistics.** Unlike for the SMR and SHR, the information provided for the STrR does not provide a straightforward global assessment of the fitted model using c-statistics. Rather, Akaike and Bayesian Information Criteria (AIC and BIC, respectively) were calculated to assess goodness-of-fit and demonstrate the value of risk adjusting the measure with the selected covariates. We note that Akaike and Bayesian Information Criteria are described in the literature as an alternative approach to the traditional hypothesis testing statistical paradigm; they are "based on information theory and thus do not generate a p-value, do not reach conclusions about statistical significance, and do not reject any model. The resulting probabilities are meaningful only in the context of comparing two or more models, and the method determines how well the data support each model being compared, taking into account both the goodness-of-fit and the number of parameters in the model."[2]

  The MJF report that the multi-covariate STrR risk model was compared to "the model with intercept only" (no additional information on the latter model was offered), and

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[2] *Interpreting AIC Model Comparison.* Available at: http://www.graphpad.com/guides/prism/6/curve-fitting/index.htm?reg_interpreting_comparison_of_mod_3.htm.

provide what appear to be raw AIC and BIC values:

- STrR model AIC value = 2837936.9; Intercept-only model AIC value = 2853811.9.
- STrR model BIC value = 2838305.9; Intercept-only model BIC value = 2853811.9

The MJF indicates "smaller values are better" and that the AIC and BIC values suggest "great value in risk adjustment" and "reflect great importance of the adjustment covariates, in aggregate."

We note, however, peer-reviewed literature describing how to interpret AIC and BIC indicate that while smaller values are indeed considered "better", it is difficult to intuit how much statistical importance should be attached to differences in raw AIC and BIC values between models. Moreover, raw values cannot convey the weight of evidence in favor of one model over another; raw values can be converted to Akaike and BIC model "weights," which can then be directly interpreted as conditional probabilities for each model.[2,3]

Given the failure to provide the more comprehensible and meaningful Akaike and BIC model weights and the lack of information on the alternative (intercept-only) model, the goodness-of-fit and the value of the selected model over the intercept-only model is not transparent and so cannot be appropriately evaluated. KCP requests additional information in this regard (e.g., AIC and BIC weights, details on the intercept-only model) and clarity on these data to allow for an appropriate analysis and interpretation of results.

5. **RELIABILITY AND VALIDITY**

Notwithstanding our concerns about the validity of the STrR to accurately reflect transfusion events, KCP still has significant concerns about the testing results using the specifications for the newly proposed STrR.

- **Reliability.** Reliability testing for the STrR yielded IURs of 0.60-0.66 across all facilities for each of 2011, 2012, 2013, and 2014. Such values indicate about 65% of the variation in a score can be attributed to between-facility differences (signal) and about 35% to within-facility differences (noise)—a moderate degree of reliability. However, when looking exclusively at small (defined as <=46) and medium (47-78) facilities, the IURs are substantially lower. Specifically, the IURs ranged from 0.30-0.41 and 0.50-0.56 for small and medium facilities, respectively, over the same time period. Not surprisingly, the reliability increases for larger facilities. We note a reliability statistic of 0.70 is often considered as "good" reliability,[4] though the characterization also depends on the analytic method. The overall reliability of the STrR falls short in this regard. We 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.

- **Validity.** The Spearman's correlation coefficients are STrR-SHR = 0.28; STrR-SMR = 0.16; STrR-SRR = 0.15; STrR-AVF = -0.11; STrR-Catheter = 0.14; STrR-Kt/V>=1.2 = -0.04; STrR-Hgb<10 = 0.21. The correlations are directionally as expected. However, KCP believes the MJF overstates these correlations, concluding, "the overall measure demonstrates both strong face validity and construct validity." By convention,

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[3] Wagenmakers EJ and Farrell S. AIC model selection using Akaike weights. *Psychonomic Bulletin and Review.* 2004;11(1):192-196.

[4] Adams, JL. The Reliability of Provider Profiling: A Tutorial. Santa Monica, California:RAND Corporation. TR-653-NCQA, 2009.

Spearman's rho of 0-0.19 appears to be considered "very weak" and must be 0.60-0.79 to be considered "strong."[5] We request the results be more accurately characterized, as they were for the SMR—i.e., that the correlations were directionally as expected.

6. RATIO VS. RATE MEASURES

As most recently noted in our comments on the SMR and SHR, 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.

7. IMPRECISION/INCONSISTENCIES IN DEFINITIONS

We have identified a number of imprecisions and inconsistencies across the STrR, SMR, and SHR measures, and request clarification on the underlying rationale.

- Inconsistent Definitions. There are significant inconsistencies in how facility size is defined when assessing reliability for the STrR, SMR, and SHR. Specifically, for STrR reliability analyses, small, medium, and large facilities were defined as <=46, 47-78, and >=79, respectively. For the SMR, the definitions were <=45, 46-85, >=86 for the 1-year reliability analyses, but were <=135, 136-305, and >=306 for the 4-year analyses. And for the SHR, <=50, 51-87, and >=88 were used.   We request clarification on the rationale for these inconsistencies and the potential impact on the reliability statistics of the measures.

  Similarly, we note the following variations in patient age and duration of ESRD groupings in the STrR, SMR, and SHR risk models:

  - Age:
    - STrR and SHR = 0-14, 15-24, 25-44, 45-59, 60-74, or 75+ years old
    - SMR = 0-13, 14-60, or 61+ years old
  - Duration of ESRD:
    - STrR and SHR = 91 days-6 months, 6 months-1 year, 1-2, 2-3, 3-5, or 5+ years as of period start date
    - SMR = <1 year, 1-2 years, 2-3 years, or 3+ years as of period start date

  We again request clarification on the rationale for these inconsistencies, as well as the potential impact on the risk models.

- **Patient-Years-at-Risk.** The facility minimum data requirement is defined as 5 patient-years-at-risk for the SHR, but appears to be 10 patient-years-at-risk for the STrR; no rationale for the difference is provided. Additionally, while the QIP version of the STrR specifications clearly indicate the 10 patient-years-at-risk requirement and documents accompanying the revised measure currently released for review indicate this definition was used for testing and performance analyses, the revised specifications neither specifically identify the requirement nor indicate that it is unchanged from previous iterations. KCP requests clarification on the minimum data requirement for the revised STrR, as well as a rationale for the different requirements for the STrR and SHR.

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).

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[5] Stats Tutor, *Spearman's Correlation*. Available at www.statstutor.ac.uk. Last accessed February 2016.

Sincerely,

AbbVie
Akebia
American Kidney Fund
American Nephrology Nurses Association
American Renal Associates
American Society of Nephrology
American Society of Pediatric Nephrology
Amgen
Astra Zeneca
Baxter
Board of Nephrology Examiners Nursing Technology
Centers for Dialysis Care
DaVita
Dialysis Clinic, Inc.
Dialysis Patient Citizens
Fresenius Medical Care
Fresenius Medicare Care Renal Therapies
Greenfield Health Systems
Keryx
Kidney Care Council
National Kidney Foundation
National Renal Administrators Association
Nephrology Nursing Certification Commission
Northwest Kidney Centers
NxStage Medical
Renal Physicians Association
Renal Support Network
Rogosin Institute
Sanofi
Satellite Healthcare
U.S. Renal Care