

Public Comment Summary Report

Project Title:

Revisions to the Standardized Transfusion Ratio (STrR)

Dates:

- The Call for Public Comment period opened on February 19, 2016 and closed on March 4, 2016.
- The Public Comment Summary was made available on March 25, 2016.

Project Overview:

The Centers for Medicare & Medicaid Services (CMS) has contracted with the University of Michigan Kidney Epidemiology and Cost Center (UM-KECC) to develop measures of anemia management in ESRD patients. The contract name is ESRD Quality Measure Development, Maintenance, and Support. The contract number is HHSM-500-2013-130171.

As part of its measure development process, CMS requests interested parties to submit comments on the candidate or concept measures that may be suitable for this project.

Project Objectives:

The specifications for the Standardized Transfusion Ratio have been revised, and we seek comment on these revisions. We developed a more conservative definition of transfusion events. The revised definition excludes inpatient transfusion events for claims that include only 038 or 039 revenue codes without an accompanying procedure or value code. In the revised measure, all inpatient transfusion events include, at a minimum, an appropriate ICD-9 Procedure Code or Value Code. This more conservative definition of transfusion events is used to calculate the restricted STrR. As expected from the information provided above, this more restricted definition of transfusion events results in a reduced total number of events identified as well as the range of total events for dialysis facilities.

Information About the Comments Received:

- Public comments were solicited by e-mail.
- 3 responses were received on this topic.

Stakeholder Comments—General and Measure-Specific

Commenters felt that the STrR unfairly punishes facilities for an outcome impacted by multiple variables beyond the facility's control, including lack of access to transfusion data and transfusions that are performed due to factors that cannot be affected by the dialysis facility (chronic illnesses, inadequate anemia management at the inpatient facility, etc).

Response: Facility level transfusion events are available to facilities through the Dialysis Facility Reports (DFRs). We appreciate the commenter's suggestion, and we will consider whether providing more frequently updated transfusion event lists is feasible and would result in actionable information for providers.

Many newer quality measures are designed to incentivize coordinated care, including hospitalization and rehospitalization metrics approved by the National Quality Forum for multiple provider types. A dialysis facility transfusion metric similarly incentivizes transfusion avoidance that is often a consequence of inadequate anemia management by dialysis facilities in a clinical context where blood loss is occurring or is anticipated in another care venue. The immediate clinical indication to transfuse blood may be beyond the control of the dialysis facility, but ultimately the need for transfusion depends both upon that immediate clinical situation and the dialysis facility's underlying anemia management.

Commenters also raised the issue of the new restricted definition of transfusion events. Commenters felt that the restricted transfusion definition is not a valid representation of transfusion events. They noted that the revision could result in increased variability in performance due to external factors (variation in hospital coding practices) and not facility performance.

Response: The definition of transfusion events used in the revised STRR measure is consistent with definitions used in numerous scientific publications and is structurally consistent with Medicare claims processing rules. By excluding transfusion events identified only through revenue code, the false positive identification of blood transfusions should be reduced, per the Medicare claims processing rules and guidelines published by the American Red Cross and other blood banking organizations. By definition, exclusion of revenue code only transfusion events decreases variation due to hospital coding practices. We have shown that this revision does not substantially alter the strong relationship between recent prior achieved hemoglobin and subsequent transfusion risk that had been previously shown by other investigators. Furthermore, we are not aware of any scientific publication that invalidates the definition of transfusion events used in this revised measure.

One commenter requested clarification about exclusion for minimum number of patients years at risk (10) required to calculate the measure.

Response: This requirement is not part of the measure specifications, but applied in the current implementation of the measure for DFC and for PY2018 QIP. The testing analyses in the Measure Justification Form (MJF) applied this requirement.

One commenter expressed concern about the incorporation of comorbidities in the measure specifications, questioning the validity of data from the 2728, the use of a comorbidity index for incident comorbidities, and the failure to incorporate prevalent comorbidities into the calculation.

Response: The 2728 data have not been shown to be invalid; several validation studies have shown that, in general, when diagnoses are reported on Form 2728, they are also present in the validation data source. However, the validation data source includes additional diagnosis events that may not be recorded on Form 2728. Form 2728 comorbidity diagnoses have been shown to be specific but less sensitive than the validated data source for several comorbidities. Their inclusion is a partial risk adjustment strategy. Recognizing this, the Technical Expert Panel recommended development of additional risk adjustment strategies that utilized prevalent comorbidities specifically related to conditions that would impact anemia management in ESRD patients. We utilize prevalent comorbidities as exclusions rather than covariates in the risk adjustment model to minimize the risk of underestimating their impact in the care of dialysis patients.

The STrR was revised to include the individual incident comorbidities from the 2728, not as an index. The specifications will be clarified to reflect this.

One commenter was concerned with the goodness of fit statistics (Akaike information criterion and Bayesian information criterion) and the interpretation of the validity analyses that were provided in the MJF.

Response: We appreciate these concerns, and plan to revise the information provided in the MJF regarding goodness of fit prior to submission to the National Quality Forum (NQF).

One commenter expressed their desire to report standardized rates instead of standardized ratios.

Response: The measure has been specified and calculated as a standardized ratio, but could be expressed as a standardized rate (as stated in the MIF for each measure). We

note that the measure will be displayed as a rate on DFC beginning in October 2016.

One commenter noted inconsistencies across definitions between the Standardized Mortality Ratio (SMR), the Standardized Hospitalization Ratio (SHR), and the Standardized Transfusion Ratio (STrR), including the grouping categories for Age and Duration of ESRD covariates in the risk models, and the grouping of facility size categories used for reliability calculations.

Response: The categories for the Age and Duration of ESRD covariates in the risk adjustment models were empirically derived when the SMR and SHR models were first developed, and are based on model fit specific to each outcome. This accounts for the use of different groupings for each model.

The STrR was developed as an adaptation of the SHR methodology, and the age groupings were left in-tact with the consideration of harmonization with SHR.

Preliminary Recommendations

Based on the comments received, no substantive material changes will be made to the measure specifications, although several comments led to improvements in the measure documentation/justification.

Overall Analysis of the Comments and Recommendations

Comments were very constructive and led to several improvements in the measure documentation. CMS and UM-KECC appreciate the time dedicated to reviewing and providing comments on this measure.

Public Comment Verbatim Report

Date Posted	Measure Set or Measure	Text of Comments	Name, Credentials, and Organization of Commenter	Type of Organization	Recommendations/Actions Taken
March 25, 2016	STrR	See appendix	Kidney Care Partners (KCP)	Professional Organization	We thank you for your feedback. Stakeholder comments will be reviewed by measure developers and taken under consideration. Responses to comment themes are provided above.
March 25, 2016	STrR	See appendix	American Nephrology Nurses Association	Professional Organization	We thank you for your feedback. Stakeholder comments will be reviewed by measure developers and taken under consideration. Responses to comment themes are provided above.
March 25, 2016	STrR	See appendix	Amgen	Pharmaceutical	We thank you for your feedback. Stakeholder comments will be reviewed by measure developers and taken under consideration. Responses to comment themes are provided above.



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March 4, 2016

VIA ELECTRONIC DELIVERY

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Centers for Medicare and Medicaid Services
Mail Stop S3-02-01
7500 Security Boulevard
Baltimore, MD 21244

University of Michigan Kidney Epidemiology Cost Center (UM-KECC)
1415 Washington Heights
Suite 3645 SPHI
Ann Arbor, MI 48109-2029

Re: Revisions to the Standardized Transfusion Ratio (STrR) - contract number HHSM-500-2013-13017I

Dear Joel:

Amgen Inc. (Amgen) appreciates the opportunity to comment on the proposed revised specifications for the STrR. As a science-based, patient-driven company committed to using science and innovation to dramatically improve people's lives, Amgen is vitally interested in improving access to innovative drugs and biologicals for Medicare beneficiaries. For more than a quarter century, Amgen has developed, manufactured, and marketed products for treatment of patients with End-Stage Renal Disease (ESRD), including products that treat chronic anemia in patients with ESRD.

The Centers for Medicare and Medicaid Services (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 would be excluded.

Amgen strongly opposes any revision to the STrR that does not first involve a rigorous evaluation of transfusion coding practices across hospitals. This can help to validate appropriate coding practices and enable a path towards standardization. This would ensure that the STrR can best serve patients on dialysis. Avoiding the need for red blood cell (RBC) transfusions is a widely recognized treatment goal and therefore an important outcome in the dialysis population. It is well-documented that the use of transfusion for the correction of

chronic anemia can result in adverse clinical consequences for patients on dialysis, including the development or increase in antibodies to human leukocyte antigens (HLA), reducing the number of potential donor organs a patient is eligible to receive, thereby reducing the number of organ offers.^{1,2,3} Consequently, patients with higher antibody levels spend more time on the transplant waiting list, are more likely to die while waiting for a transplant, and – for patients who receive a transplant – are subject to shortened graft survival.^{4,5,6} In addition, transfusions have been shown to be associated with additional adverse clinical consequences, including the transmission of blood-borne diseases, an increased risk of iron overload, and an increased risk of hospitalization due to hyperkalemia or heart failure (volume overload).⁷ Recognizing the importance of appropriate anemia management for patients on dialysis and the associated clinical risks when inadequately treated, Congress required that the ESRD Quality Incentive Program (QIP) include measures on anemia management reflecting product labeling for anemia therapies.

The STrR measure is an important metric to deter anemia under-treatment. This measure highlights the importance of transfusion avoidance when caring for a patient receiving dialysis. Therefore, CMS should embark on an effort to rigorously investigate current practices in order to advance more standardization within hospitals to ensure that the STrR is appropriate for evaluating dialysis facility anemia management. The revision as proposed will likely have unintended consequences that include an overall under-reporting of transfusion and a re-distribution of dialysis center performance on the STrR. By CMS's own admission, this more restricted definition of transfusion events will reduce the total number of events identified, without providing any rationale to support the appropriateness of the reductions and seemingly without regard for the impact it may have on the care of the ESRD population.⁸

It is well accepted that the vast majority of transfusions occur in the hospital setting,⁹ and is also well accepted that hospital coding practices for transfusion events vary significantly. Currently, there are no requirements for transfusion coding practices across U.S. hospitals; resulting in substantial variability, as evidence in Table 1 below. These data from calendar year (CY) 2012 show the distribution of transfusion codes used across U.S. hospitals and indicate 88,203 fewer transfusion events would be identified if the proposed changes were accepted.¹⁰ If the STrR revisions are implemented as described, the performance of dialysis centers across the country will change significantly; for those whose billing practices do not include revenue codes, this could immediately translate to penalties because their STrR would undoubtedly increase.

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- 1 Yabu, et al: *Nephrol Dial Transplant*. 2013;28: 2908-2918.
 - 2 Leffell, Kim, et al. *Transplantation*. 2014;97(5): 525-533.
 - 3 Organ Procurement and Transplantation Network (OPTN) Proposal to Substantially Revise the National Kidney Allocation System. 2012. (Accessed 6/17/2013, at http://optn.transplant.hrsa.gov/PublicComment/pubcommentPropSub_311.pdf.)
 - 4 Lietz K, Lao M, Paczek L, et al. *Ann Transplant*. 2003;8(2):17-24.
 - 5 UNOS: United Network for Organ Sharing. <http://www.unos.org/>. Accessed February 25, 2016.
 - 6 Opels. *The Lancet*. 2005;1570 1576.
 - 7 Gill et al., *Pharmacoepidemiology & Drug Safety*, 2015.
 - 8 CMS Quality Measures Public Comment Page. <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/MMS/CallforPublicComment.html#18> accessed on February 25, 2016.
 - 9 Ibrahim HN, Ishani A, Foley RN, Guo H, Liu J and Collins AJ: *Am J Kidney Dis*. 2008;52: 1115-1121.
 - 10 Amgen, Data on File.

Table 1. The number of transfusions identified in CY 2012 based on the current and the proposed, more conservative, definitions (CY 2012 ESRD Medicare data)¹¹

	Current definition	Proposed definition	% change (proposed vs. current)
Total transfusions	271,274	183,071	-32.5%
Inpatient	216,082	138,737	-35.8%
-ICD-9 procedure code	133,149	133,149	
-Value code	5,588	5,588	
-Revenue code	77,345	-	
Outpatient	55,192	44,334	-19.7%
-HCPCS code	43,451	43,451	
-Value code	883	883	
-Revenue code	10,858	-	

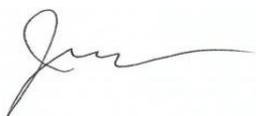
Amgen recognizes that not all transfusions may be related to dialysis facility performance, yet proposing coding requirements to the STrR in the absence of any such requirement on the hospital will result in significant threats to the measure’s validity rather than address the issue of attribution of transfusion as a measure of dialysis facility performance. The proposed change will differentially impact facilities, and providers will no longer be measured based on the anemia management of their patients, but based on the billing practices of the hospitals where their patients received transfusions. For facilities in areas where hospitals do use procedure or value codes, the facilities could appear to have “poor” performance because of higher than expected numbers of transfusions. Conversely, in areas where hospitals do not use procedure or value codes, those facilities could appear to have “good” performance because of lower than expected or no transfusions recorded.

Amgen believes that until there is a standardized method for hospital reporting of transfusion events, it does not make sense to revise the STrR measure specifications as proposed and therefore recommends that CMS not implement the proposed revisions.

¹¹ Amgen, Data on File.

Amgen appreciates the opportunity to provide these comments. Please contact me by phone at (202) 585-9659 or by email at jspangle@amgen.com if you have any questions. Thank you for your attention to this important matter.

Regards,

A handwritten signature in black ink, appearing to read 'Jason', with a long horizontal flourish extending to the right.

Jason Spangler, MD, MPH

Executive Director, U.S. Health Policy and Reimbursement



March 4, 2016

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University of Michigan Kidney Epidemiology and Cost Center 1415 Washington Heights
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dialysisdata@umich.edu

Re: Revisions to the Standardized Transfusion Ratio

Dear Sir or Madam:

On behalf of the American Nephrology Nurses Association (ANNA), I appreciate the opportunity to comment on the Centers for Medicare and Medicaid Services (CMS) and University of Michigan Kidney Epidemiology and Cost Center's (UM-KECC) proposed revisions to the Standardized Transfusion Ratio (STrR). ANNA is supportive of CMS and UM-KECC's efforts to develop measures of anemia management in End-Stage Renal Disease (ESRD) patients.

ANNA promotes excellence in and appreciation of nephrology nursing so that we can make a positive difference for people with kidney disease. Established as a nonprofit organization in 1969, ANNA has a membership of approximately 9,000 registered nurses in almost 100 local chapters across the United States. We are the only professional association that represents nurses who work in all areas of nephrology, including hemodialysis, chronic kidney disease, peritoneal dialysis, acute care, and transplantation. Most of our members work in freestanding dialysis facilities, hospital outpatient units, and hospital inpatient dialysis units.

ANNA develops and updates standards of clinical practice, educates practitioners, stimulates and supports research, disseminates knowledge and new ideas, promotes interdisciplinary communication and cooperation, and monitors and addresses issues encompassing the breadth of practice of nephrology nursing.

We are supportive of CMS and UM-KECC's efforts to revise the STrR and we appreciate CMS and UM-KECC's efforts to limit the definition of a transfusion event. The revisions to the STrR, however, fail to adjust for multiple variables, and ANNA has several concerns regarding the STrR measure.

ANNA believes that implementation of the STrR as currently drafted will hold outpatient dialysis facilities responsible for a measure for which they do not have data access. Few, if any, transfusions are administered in a dialysis facility, and communication with hospitals is problematic. Often, it is difficult for a dialysis facility to obtain a patient's blood transfusion data from a hospital, and impossible to acquire such

information in time to plan the continued care of that patient. ANNA supports regulations that increase the sharing of patient information between hospitals and dialysis facilities and that reduce the risks for dialysis patients. As CMS proceeds with implementation of the STTrR, ANNA encourages CMS to require hospitals to promptly transmit dialysis patients' transfusion data upon discharge to the dialysis facilities involved in the care of such patients. The sharing of blood transfusion data and other related information will allow for safer and more effective care of patients.

ANNA also has concerns the STTrR fails to take into consideration the reasons for the transfusion. Often, it is unclear why dialysis patients receive transfusions. For example, in the experience of our members, hospitals frequently do not continue erythropoiesis-stimulating agent (ESA) doses during a patient's hospitalization, which can lead to the need for transfusion. Additional grounds for transfusion include inadequate anemia management in the inpatient facility, other chronic illness, or due to an acute problem during hospitalization. These factors are both outside the control of and unrelated to the care provided in a dialysis facility.

We are concerned that the use of the STTrR as a clinical measure may unfairly punish a facility for an outcome impacted by multiple variables beyond its control. We urge CMS and UM-KECC to consider the influence of such patient-specific conditions on the calculation of the STTrR and further examine methods to eliminate the effect of such variables on each facility's STTrR.

ANNA greatly appreciates the opportunity to share our comments on the revisions to the STTrR. As the leading professional association representing nephrology nurses, we look forward to continuing to work with you and CMS on these important issues. Should you have any questions, please contact me or have your staff contact our Health Policy Consultant, Kara Gainer (Kara.Gainer@dbr.com or 202-230-5649). We thank you for your consideration.

Sincerely,



Cindy Richards, BSN, RN, CNN
President, 2015-2016



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

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

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:

- STTrR model AIC value = 2837936.9; Intercept-only model AIC value = 2853811.9.
- STTrR 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 STTrR to accurately reflect transfusion events, KCP still has significant concerns about the testing results using the specifications for the newly proposed STTrR.

- **Reliability.** Reliability testing for the STTrR 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 STTrR 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 STTrR-SHR = 0.28; STTrR-SMR = 0.16; STTrR-SRR = 0.15; STTrR-AVF = -0.11; STTrR-Catheter = 0.14; STTrR-Kt/V ≥ 1.2 = -0.04; STTrR-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,

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).

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