CBE ID

2979

Title

Standardized Transfusion Ratio for Dialysis Facilities

Project

Advanced Illness and Post-Acute Care

Endorsement Status

Endorsed

Is Under Review

No

Next Maintenance Cycle

Fall 2030

Previous Endorsement Cycle

Fall 2025

Initial Endorsement

Fri, 12/09/2016 - 05:43

Steward

Centers for Medicare & Medicaid Services

1.0 New or Maintenance

Maintenance

1.1 Measure Structure

Single Measure

1.3 Electronic Clinical Quality Measure (eCQM)

No

1.6 Measure Description

The risk adjusted facility level Standardized Transfusion Ratio (STrR) is specified for all adult dialysis patients. It is a ratio of the number of eligible red blood cell transfusion events observed in patients dialyzing at a facility, to the number of eligible transfusion events that would be expected under a national event rate, after accounting for the patient characteristics within each facility.

1.6a Material Specification Change(s)

Yes

1.6b Summary of Specification Changes

Since the previous endorsement cycle, we have made the following changes:

1. Denominator: the measure now includes Medicare Advantage (MA) patients that had previously been excluded due to lack of claims data.
2. Exclusion criteria: the measure no longer excludes patients with certain coagulation disorders, hereditary anemias, or malignancies since our analyses indicate that these patients receive erythrocyte stimulating agents as part of their anemia management strategy. The measure now risk adjusts for these comorbidities.
3. Risk Adjustment: the measure now risk adjusts for certain coagulation disorders, hereditary anemias, or malignancies that had previously been excluded.
4. Risk Adjustment: based on stakeholder feedback, the measure now risk adjusts for certain comorbidities that indicate a history of gastrointestinal bleeding.

1.7 Measure Type

Outcome

1.8 Level of Analysis

Facility

1.9 Care Setting

Other

1.9b Other Care Setting

Dialysis Facility

1.10 Measure Rationale

End Stage Renal Disease (ESRD) is associated with severe anemia, historically often requiring repeated blood transfusions. With the introduction of erythropoiesis stimulating agents (ESAs; e.g. erythropoietin alpha, darbepoetin, etc.) in the late 1980’s, transfusion events in ESRD patients declined dramatically. Responsibility for anemia management was assigned to the treating dialysis facility by CMS regulation and also by specific payment policy and has remained so since that time. Safety concerns arising from clinical trials of ESA treatment of anemia of chronic kidney disease (CKD) led to changes in FDA recommendations on ESA use in patients with CKD. In addition, changes in financial incentives for treatment of anemia following the implementation of the revised Medicare ESRD Prospective Payment System in 2011 further heightened concerns in the dialysis community that patients with CKD-related anemia would be denied adequate access to ESAs for prevention of red blood cell transfusion. This concern was confirmed by subsequent trends in anemia management in US chronic dialysis patients, demonstrating rapid declines in achieved hemoglobin from mid-2010, just prior to implementation of the Expanded ESRD Prospective Payment System in 2011 and increasing transfusion rates in the 2011-2014 time period. The FDA Prescribing Information for EPO and other ESAs state that blood transfusion avoidance is the primary goal of treatment with these agents. A specific achieved hemoglobin target is not recommended in the Prescribing Information.

Dialysis facilities, as the primary assigned anemia managers for this patient population are charged with the difficult task of optimizing ESRD patients' anemia, striking a balance between avoidance of the risks of over-treatment against the risk of developing symptomatic anemia and requirement for blood transfusion. This clinical responsibility is shared with other institutional providers (e.g. acute care hospitals) when ESRD patients are admitted to the hospital for any reason and care coordination in such situations is ideal. In particular, patients undergoing invasive procedures, or those with acute infectious illnesses causing or contributing to the hospitalization, may require blood transfusion. Since the decision to transfuse blood is often made by the treating inpatient team, albeit using well-established criteria for blood transfusion, there is shared responsibility for the transfusion event. The anemia management preceding the acute illness or hospitalization contributes to the starting hemoglobin level as well as to the transfusion risk. Furthermore, the subsequent acute care and medical situation also contributes to this risk. Given the clear responsibility of overall anemia management assigned to the dialysis facility and the clear associations between facility anemia management with both achieved hemoglobin and transfusion risk, this measure is useful as an indicator of successful use of ESAs and HIF protease inhibitors as indicated by the FDA, at reducing the risk of unnecessary blood transfusion (and associated risks, including allosensitization to HLA antigens).

It has been postulated that a national trend toward increased use of transfusions in dialysis patients would adversely affect the supply of blood available for acute injuries and surgical procedures in other patients. Lastly, greater exposure to human leukocyte antigens, present in transfused blood, may increase anti-HLA antibodies in kidney transplant candidates, resulting in reduced access to kidney transplantation.

The inverse relationship between achieved hemoglobin and risk for blood transfusion has been reported previously. In addition, the dialysis facility's anemia management processes also predict adverse outcomes associated with anemia management, including need for blood transfusion. These issues are discussed in the Evidence Form included as part of this submission.

1.13 Data Dictionary

Attached

1.13a Attach Data Dictionary

STrR_Dic_Code_List_Final_Oct-2025.xlsx

1.14 Numerator

The numerator is the number of eligible observed red blood cell transfusion events. An event is defined as the transfusion of one or more units of red blood cells into a recipient's blood stream (code set is provided in the numerator details) among patients dialyzing at the facility during the reporting period.

1.14a Numerator Details

Transfusion events in the inpatient setting are counted in the following way. The event is identified by presence in a Medicare Part A inpatient claims and Part C inpatient encounter data of the appropriate ICD procedure codes (99.03, 99.04, 30230H1, 30230N1, 30230P1, 30233H1, 30233N1, 30233P1, 30240H1, 30240N1, 30240P1, 30243H1, 30243N1, 30243P1, 30250H1, 30250N1, 30250P1, 30253H1, 30253N1, 30253P1, 30260H1, 30260N1, 30260P1, 30263H1, 30263N1, 30263P1, 302A3H1, 302A3N1, 302A3P1), or revenue center codes (0380, 0381, 0382, 0389, 0390, 0391, 0392, 0399) or value code (37). We only count a single transfusion event for an inpatient claim regardless of the number of transfusion revenue center, procedure, and value codes reported so that the number of discrete events counted is the same whether the claim indicates one unit of blood or multiple units of blood. This results in a more conservative estimate of blood transfusions from inpatient claims.

Transfusion events are less common in the outpatient setting. Transfusion events in the outpatient setting are counted in the following way. Events derived from Medicare Part B outpatient claims and Part C outpatient encounter data are identified by claims with HCPCS code (P9010, P9011, P9016, P9021, P9022, P9038, P9039, P9040, P9051, P9054, P9056, P9057, P9058, 36430) with revenue center codes in (0380, 0381, 0382, 0389, 0390, 0391, 0392, 0399) or value code (37). One or more transfusion-related HCPCS codes with at least one transfusion-related revenue center codes, or one or more transfusion-related value codes listed on an outpatient claim are counted as a single transfusion event regardless of the number of units of blood recorded. In other words, three units of blood would be counted as a single transfusion event.

In addition, we combine the transfusion claims with overlapping periods into a single claim, and only count one transfusion event from each claim. The transfusion event for a particular claim is treated as having occurred on last day of that claim.

The detailed procedures to determine unique transfusion events at the claim level are presented in a flow chart. See the second page of the **STrR_Flowchart_Final_Oct_2025_508** PDF, attached to 1.18a.

1.15 Denominator

The denominator is the number of eligible red blood cell transfusion events that would be expected among patients at a facility during the reporting period, given the patient mix at the facility.

1.15a Denominator Details

Assignment of Patients to Facilities

The ESRD Quality Reporting System (EQRS), including CMS Medical Evidence Form (Form CMS-2728) and Death Notification Form (Form CMS-2746) is the primary basis for placing patients at dialysis facilities. Outpatient dialysis claims are used as an additional source when needed. We create a complete history of the status, location, and dialysis treatment modality of an ESRD patient from the date of the first ESRD service until the patient dies or the data collection cutoff date is reached. A new record is created each time a patient changes facilities or dialysis treatment modality; therefore, each record represents a time period associated with a specific modality and dialysis facility. Information regarding first ESRD service date, death and transplant is obtained from additional sources including the CMS Enrollment Database (EDB), transplant data from the Organ Procurement and Transplant Network (OPTN), and the Social Security Death Master File.

We detail patient inclusion criteria, facility assignment and how to count days at risk, all of which are required for the risk adjustment model. As patients can receive dialysis treatment at more than one facility in a given year, we assign each patient day to a facility (or no facility, in some cases) based on a set of conventions below.

General Inclusion Criteria for Dialysis Patients

Patients are included in the measure only after they have had ESRD for greater than 90 days. This minimum 90-day period assures that patients are eligible for Medicare, either as their primary or secondary insurer, and that follow-up is complete. Thus, the measure excludes transfusion events during the first 90 days of ESRD as well as patients who die or recover kidney function during that time period.

In order to exclude patients who only received temporary dialysis therapy, we assign patients to a particular facility only after they have been on chronic dialysis there for the past 60 days. This 60-day period is used both for patients who started ESRD for the first time and for those who returned to dialysis after a transplant. That is, transfusion events during the first 60 days of dialysis at a facility do not affect the STrR of that facility.

In order to assure completeness of information on transfusions for all patients included in the analysis, we restrict to Medicare patients who are either enrolled in Medicare Advantage or who reach a certain threshold of Medicare dialysis and inpatient claims. Specifically, months within a given dialysis patient-period are used for STrR calculation when the patient is enrolled in Medicare Advantage or meets the criterion of being within two months after a month with either: (a) $1200+ of Medicare-paid dialysis claims OR (b) at least one Medicare inpatient claim.

Identifying Facility Treatment Histories for Each Patient

For each patient, we identify the dialysis provider at each point in time. Starting with day 91 after onset of ESRD, we attribute patients to facilities according to the following rules. A patient is attributed to a facility once the patient has been treated there for the past 60 days. When a patient transfers from one facility to another, the patient continues to be attributed to the original facility for 60 days and then is attributed to the destination facility. In particular, a patient is attributed to his or her current facility on day 91 of ESRD if that facility had treated him or her for the past 60 days. If on day 91, the facility had not treated a patient for the past 60 days, we wait until the patient reaches day 60 of continuous treatment at that facility before attributing the patient to that facility. When a patient is not treated in a single facility for a span of 60 days (for instance, if there were two switches within 60 days of each other), we do not attribute that patient to any facility. Patients are removed from facilities three days prior to transplant in order to exclude the transplant hospitalization. Patients who withdrew from dialysis or recovered renal function remain assigned to their treatment facility for 60 days after withdrawal or recovery.

If a period of one year passes with neither paid dialysis claims nor EQRS information to indicate that a patient was receiving dialysis treatment, we consider the patient lost to follow-up and do not include that patient in the analysis. If dialysis claims or other evidence of dialysis reappears, the patient is entered into analysis after 60 days of continuous therapy at a single facility.

Days at Risk for Medicare Dialysis Patients

After patient treatment histories are defined as described above, periods of follow-up in time since ESRD onset are created for each patient. In order to adjust for duration of ESRD appropriately, we define six, time intervals with cut points at 6 months, 1 year, 2 years, 3 years and 5 years. A new time period begins each time the patient is determined to be at a different facility, or at the start of each calendar year or when crossing any of the above cut points.

The number of days at risk in each of these six, time intervals listed above is used to calculate the expected number of transfusions for the patient during that period. The STrR for a facility is the ratio of the total number of observed transfusions to the total number of expected transfusions during all time periods at the facility. Based on a risk adjustment model for the overall national transfusion rates, we compute the expected number of transfusions that would occur for each month that each patient is attributed to a given facility. The sum of all such expectations for patients and months yields the overall number of transfusions that would be expected given the specific patient mix. This forms the denominator of the measure.

The denominator of the STrR is derived from a proportional rates model [4] [5] [3]. This is the

recurrent event analog of the well-known proportional hazards or Cox model [2] [3]. To accommodate large-scale data, we adopt a model with piecewise constant baseline rates [1] and the computational methodology developed for clustered recurrent event data [6].

References

[1] Cook, R. and Lawless, J. The Statistical Analysis of Recurrent Events. New York: Springer. 2007.

[2] Cox, D.R. (1972) Regression Models and Life Tables (with Discussion). J. Royal statistical Society, Series B, 34, 187-220.

[3] Kalbfleisch, J.D. and Prentice, R. L. The Statistical Analysis of Failure Time Data. Wiley, New York, 2002.

[4] Lawless, J. F. and Nadeau, C. Some simple and robust methods for the analysis of recurrent events, Technometrics, 37 1995, 355-364.

[5] Lin, D.Y., Wei, L.J., Yang, I. and Ying, Z. Semi parametric regression for the mean and rate functions of recurrent events, Journal of the Royal Statistical Society Series B, 62, 2000, 771-730

[6] Liu D, Schaubel DE, Kalbfleisch JD. Computationally efficient marginal models for clustered recurrent event data. *Biometrics*. 2012

1.15b Denominator Exclusions

Exclusions that are implicit in the denominator definition include:

- Time at risk while a patient has had ESRD for 90 days or less
- <18 years old
- Non-Medicare primary insurance

1.15c Denominator Exclusions Details

See Denominator Details, 1.15a above

1.15d Age Group

Adults (18-64 years), Older Adults (65 years and older)

1.16 Type of Score

Ratio

1.17 Measure Score Interpretation

Better performance = Lower score

1.18 Calculation of Measure Score

The numerator is the observed number of transfusion events for a facility, and the denominator for the same facility is the expected number of transfusion events adjusted for patient mix. The measure for a given facility is calculated by dividing the numerator by the denominator. See **STrR_Flowchart_Final_Oct_2025_508** PDF, attached to 1.18a, for further detail.

1.18a Attach measure score calculation diagram

STrR_Flowchart_Final_Oct_2025_508.pdf

1.19 Measure Stratification Details

This measure wasn't stratified.

1.20 Types of Data Sources

Administrative Data, Claims Data, Registries

1.21a Data Collection Tool URL(s)

http://example.com

1.25 Data Source Details

Data are derived from the EQRS patient-specific clinical and administrative data, including ESRD patient list, CMS-2728 Medical Evidence Form, CMS-2746 Death Notification Form, and patient admission and discharge data, from all Medicare certified dialysis facilities, the Medicare Enrollment Database (EDB), and Medicare claims data.

In addition, the database includes transplant data from the Scientific Registry of Transplant Recipients (SRTR), data from the Nursing Home Minimum Dataset, and the provider and survey and certification data from the Internet Quality Improvement and Evaluation System (iQIES) data.

Information on transfusions is obtained from inpatient and outpatient claims of Standard Analysis Files (SAFs), and past-year comorbidity data are obtained from multiple claim types (inpatient, outpatient, home health, hospice (Part A only), skilled nursing facility claims, and physician supply).

Fee-for-service (FFS) Medicare Part A (inpatient) and Part B (outpatient and physician supply) claims for dialysis patients are included in the current database; additionally, the measure now incorporates Part C Medicare Advantage (MA) data for the MA enrollees. This ensures that hospital, outpatient dialysis, and other billable services under Medicare – whether FFS or MA – are captured.

1.26 Minimum Sample Size

Public reporting of this measure on DFCC or in the ESRD QIP would be restricted to facilities with at least 10 patient years at risk for the measure to comply with restrictions on reporting of potentially patient identifiable information related to small cell size. We have applied this restriction to all the reliability and validity testing reported here.

2.1 Attach Logic Model

STrR-Logic-Model_Final_Oct-2025_508_revised.pdf

2.2 Evidence of Measure Importance

See **STrR_2.2_Final_Oct 2025_508_revised** PDF, attached in Section 7.1 Supplemental Attachment, for full response to this question.

2.4 Performance Gap

Data are from the dataset described in section 1.25 for year 2023. The total number of dialysis facilities included in the performance scores was 7,268. The total number of patients included in the performance scores was 473,742.

See **STrR_2.4 Table 1_Final_Oct 2025_508** PDF, attached to 2.4a, for Table 1 data and caption.

2.4a Attach Performance Gap Results

STrR_2.4-Table-1_Final_Oct-2025_508.pdf

2.6 Meaningfulness to Target Population

There is at least one study indicating that patients with kidney failure who require dialysis value an assessment of red blood cell transfusion risk associated with dialysis facilities. In a discreet

choice experiment of 200 dialysis patients [1], participants were willing to accept a 6% medication-related risk of heart attack to avoid having two red blood cell transfusions per month. Overall, the study reported that patients on dialysis had clear preferences for anemia management to reduce symptoms and reduce the frequency of red blood cell transfusions.

References

[1] Hauber B, Caloyeras J, Posner J, Brommage D, Tzivelekis S, Pollock A. Hemodialysis patients' preferences for the management of anemia. BMC Nephrol. 2017 Jul 28;18(1):253. doi: 10.1186/s12882-017-0664-9. PMID: 28750609; PMCID: PMC5532766.

3.1 Contributions Towards Closing Care Gaps

Closing Care Gaps is not required for the Fall 2025 cycle.

4.1a Data Structure and Availability

All the data incorporated into our database come from structured data. Data collection for this measure is accomplished via data sources including EQRS, a web-based and electronic batch submission platform maintained and operated by CMS contractors, Medicare Claims, and other supplemental data sources (see Section 1.25 Data Source Details). Publicly reported measures like this one are reviewed on a regular basis by dialysis facility providers. Only rare instances of inaccurate or missing data are present (based on comments received during facility previews).

4.1b Implementation Costs and Burden

As the data required for this measure is already part of routine data collection, no additional costs or burden are anticipated.

4.1c Confidentiality

Public reporting of this measure on DFCC or in the ESRD QIP would be restricted to facilities with at least 10 patient years at risk for the measure to comply with restrictions on reporting of potentially patient identifiable information related to small cell size.

4.3 Feasibility Informed Final Measure

No feasibility challenges have been identified that resulted in a change to the measure. Changes to the measure were made to broaden the number of eligible patients and facilities as a consequence of new administrative data sources becoming available AND internal analyses that

identified different anemia management practices that challenged our original assumptions (from 2015) when the measure was first developed. These measure specification changes relate to elimination of some previous exclusions and do not require additional data submission by providers. The feasibility profile is not affected by the changes made.

4.4 Proprietary Information

Not a proprietary measure and no proprietary components

5.1.1 Data Used for Testing

Data from January – December 2023 was used to calculate STrR. Please refer to Section 1.25 Data Source Details for information on data sources.

5.1.1a Dates of Testing Data

January – December 2023

5.1.2 Differences in Data

None

5.1.3 Characteristics of Measured Entities

Number of facilities included for testing and analysis for the year 2023

Year: 2023

# of Facilities: 7,268

Mean Facility size (patients): 71.0

Mean Facility Patient Years: 48.8

5.1.4 Characteristics of Units of the Eligible Population

See **STrR_5.1.4_Final_Oct 2025_508** PDF, attached in Section 7.1 Supplemental Attachment, for full response to this question

5.2.1 Level(s) of Reliability Testing Conducted

Accountable entity level (i.e., measure score) (e.g., signal-to-noise analysis)

5.2.2 Method(s) of Reliability Testing

The reliability of the STrR was assessed using data among ESRD dialysis patients during 2023. 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 measure variability that is attributable to the between-facility variance. The STrR, 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.

Here we describe our approach to calculating IUR. Let $T_1,\ldots,T_N$ be the STrR 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 ith facility has n_i subjects, randomly draw with replacement n_i subjects from those in the same facility, find their corresponding $STrR_i$ and repeat the process B (say, 100) times. Thus, for the ith facility, we have bootstrapped STrRs of $T^*_1,\ldots,T^*_{100}$ ..., Let S_i^{*2} be the sample variance of this bootstrap sample. From this it can be seen that

$$S_{t,w}^2 = \Sigma^N_{i=1}[(n_i-1)\, S_i^{*2}]/\, \Sigma^N_{i=1}(n_i-1)$$

is a bootstrap estimate of the within-facility variance in the STrR, 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

$$S_t^2 = \Sigma^N_{i=1}[n_i\,(T_i - \check{T})^2]/\,[n'(N-1)],$$

where

$$\check{T} = Sn_i T_{i\,/}\, Sn_i$$

is the weighted mean of the observed STrR and

$$n' = (Sn_i - Sn_i^2/Sn_i)/(N-1)$$

is approximately the average facility size (number of patients per facility). Note that S_t^2 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 IUR = $\sigma_b^2/(\sigma_b^2 + \sigma_{t,w}^2)$ can be estimated by $(S_t^2 - S_{t,w}^2)/S_t^2$.

The STrR calculation only included facilities with at least 10 patient years at risk.

5.2.3 Reliability Testing Results

The overall IUR for the sample dataset was 0.45. The IUR's per deciles of patients ranged from 0.10 to 0.64. The overall IUR of 0.45 indicates 45% of variation in the overall measure can be attributed to between facility variations. Please see **STrR_5.2.3a Table 2_IUR Reliability Results_Revised Nov 2025_508** in Section 5.2.3a for additional information but to summarize:

- Dialysis facilities are extremely small compared to other health care entities (e.g. hospitals, nursing homes) such that risk adjusted measures do not have a large enough facility size to achieve an IUR of 0.6
- Determining if a facility is "worse than expected" uses statistical hypothesis testing to mitigate the risk of inappropriately flagging small facilities. Specifically, smaller facilities need to have an STrR farther from the median to be flagged compared to larger facilities.
- Star Ratings for dialysis facilities combine information across multiple measures to reduce random noise so that even a measure with a low IUR can contribute to raising the overall reliability of the combined measure set.
- The Quality Incentive Program (QIP) uses a small-facility adjuster (generally applied to facilities with 25 or fewer eligible patients), which helps mitigate the low IURs that would otherwise contribute to payment reductions.
- The number of preventable events, even for facilities in the lower IUR decile groups, is generally >3, suggesting the potential for improvement at a given facility.

5.2.3a Attach Additional Reliability Testing Results

STrR_5.2.3a-Table-2_IUR-Reliability-Results_Revised-Nov-2025_508.pdf

5.2.4 Interpretation of Reliability Results

This value of IUR indicates a moderate degree of reliability. The results support an inference of reliability because the measure demonstrated moderate internal consistency. When stratified by facility size, we find that, as expected, larger facilities have greater IUR. To better understand the characteristics of entities with low and high reliabilities, the boxplot included in 5.2.3a (see **STrR_5.2.3a Table 2_IUR Reliability Results_Revised Nov 2025_508** PDF) displays the distribution of STrRs across decile groups. In general, the STrR distributions are similar across decile groups, with the median STrR remaining close to 1 in all cases.

In addition, while smaller facilities naturally have measure values that exhibit greater uncertainty

and variation, statistical hypothesis testing methods account for this variability and flag only providers with truly extreme results. To illustrate the benefit of including more facilities in the STrR evaluation, we also analyzed preventable events. These results (attached in 5.2.3a) suggest that even smaller facilities in low-reliability groups still have a high average burden of adverse events, supporting the case for broader inclusion in STrR-based quality improvement programs.

See **STrR_5.2.3a Table 2_IUR Reliability Results_Revised Nov 2025_508** PDF, attached to Section 5.2.3a, for Table 2 data and caption.

5.3.1 Level(s) of Validity Testing Conducted

Accountable entity level (i.e., measure score) (e.g., criterion validity)

5.3.2 Type of Accountable Entity Level Validity Testing Conducted

Empirical validity testing at the accountable entity-level (e.g., criterion validity, construct validity, known groups analysis)

5.3.3 Method(s) of Validity Testing

Validity was assessed using Poisson regression models to measure the association between the facility level 2023 Standardized Mortality Ratio (SMR, NQF 0369) and 2023 Standardized Hospitalization Ratio (SHR, NQF 1463) and tertiles of 2023 STrR. Facility-level STrR were divided into tertiles (T1 to T3) and the relative risk (RR) of mortality was calculated for each tertile, using T1 as the reference group. Similar calculation was performed for hospitalization. Thus, a RR>1.0 would indicate a higher relative risk of mortality or hospitalization, compared to the highest performance tertile (T1) of STrR. We expect the risk of mortality and hospitalization, respectively, will be positively associated with higher tertiles of STrR.

Validity was also assessed using a Poisson regression model to measure the association between facility level STrR and tertiles of % of patients with Hgb < 10. Facility-level % of patients with Hgb < 10 in 2023 were divided into tertiles (T1 to T3) and relative risk (RR) of transfusions were calculated for each tertile, using T1 as the reference group. Thus, a RR > 1.0 would indicate a higher relative risk of transfusion, compared to the highest performance tertile (T1) of % of patients with Hgb < 10. We expect the risk of a transfusion event will be positively associated with higher tertiles of % of patients with Hgb < 10.

5.3.4 Validity Testing Results

See **STrR_5.3.4_Final_Oct 2025_508** PDF, attached to 5.3.4a

5.3.4a Attach Additional Validity Testing Results

STrR_5.3.4_Final_Oct-2025_508.pdf

5.3.5 Interpretation of Validity Results

Results from the Poisson models indicated that the STrR was significantly associated with the risks of mortality and hospitalization.

For the 2023 SMR, the relative risk of mortality increased as the STrR tertiles increased from the reference group (tertile 1). For tertile 2, RR=1.05 (95% CI: 1.04, 1.06; p<0.001), and for tertile 3, RR=1.11 (95% CI: 1.11, 1.12; p<0.001).

Similarly, for the 2023 SHR, the relative risk of hospitalization increased as the STrR tertiles increased from the reference group (tertile 1) with the lowest risk in tertile 1. For tertile 2, RR=1.13 (95% CI: 1.12, 1.14; p<0.001), and for tertile 3, RR=1.26 (95% CI: 1.25, 1.27; p<0.001).

Results from the Poisson model indicated that the % of patient months with Hgb < 10g/dl was significantly associated with the risks of transfusion as expressed in facility-level Standardized Transfusion Ratio.

The facility average STrR increased as the tertiles of % of patients with Hgb < 10g/dl increased from the reference group (tertile 1). For tertile 2, RR=1.18 (95% CI: 1.16, 1.19; p<0.001), and for tertile 3, RR=1.37 (95% CI: 1.36, 1.39; p<0.001).

5.4.1 Methods Used to Address Risk Factors

Statistical risk adjustment model with risk factors

5.4.2 Conceptual Model Rationale

Several approaches were involved in our exploration of potential risk adjustment. The current endorsed version of STrR includes some patient demographic, incident comorbidity, and clinical status risk adjustment covariates determined from internal analyses performed during prior submission work in 2016 and 2019. In addition, we re-evaluated several socio-demographic risk variables (sex, race, ethnicity, Medicare/Medicaid dual eligibility, and the effect of Area Deprivation Index) on risk of transfusion event. Most of these SDS risk variables had been considered for inclusion during our 2019 re-evaluation for NQF, but we chose NOT to include because of very limited effect of their inclusion on facility-level results. We chose to re-evaluate these factors since we are including another large group of patients (Medicare Advantage) that were excluded previously and we wanted to verify our prior analyses and check for interactions between the SDS variables and the new Medicare Advantage covariate.

Our updated literature review and several supplemental literature searches performed during this

re-evaluation were used to identify factors (sex; race) for consideration. Female sex was identified in the pre-ESA era as being associated with lower achieved hemoglobin and increased transfusion risk, attributed largely to relative absence of testosterone. In the pre-ESA era, exogenous testosterone was often administered to both female and male patients with high transfusion requirements for its erythropoietic effect. In the ESA era of CKD anemia management, female sex has been associated with higher ESA requirements and sometimes with lower achieved hemoglobin. Black race has been variably associated with decreased achieved hemoglobin and/or increased ESA requirement in the literature, and was included in our analyses on that basis. Of note, there is some evidence and more speculation that some of the race effect could be related to hereditary anemias (e.g. sickle cell disease or trait, hgb C disease, beta-thalassemias, etc.)

Finally, public commenters during prior measure re-evaluation cycles and from other public comment opportunities for specific use cases (e.g. ESRD QIP) have suggested risk-adjustment for GI bleeding. During this re-evaluation, we developed a set of ICD10 diagnosis codes that defined GI/GU bleeding (acute or chronic) which was included in risk adjustment testing.

Potential Risk Adjustment Factors Tested

- Age groups
- Cause of ESRD
- Duration of ESRD
- Nursing Home Status (none; <90 d; >=90 d)
- BMI (at incidence; categorical)
- Incident Comorbidities (from Medicare Form 2728)
- Prevalent Comorbidity Groups (Previous Exclusion Categories for malignancies, hereditary anemias, coagulation disorders)
- h/o GI/GU Bleeding from Medicare Claims and Medicare Advantage Encounter Data
- active MA insurance variable
- Interaction tests
- Duration of ESRD with Diabetes as ESRD cause
- Age groups with DM as ESRD cause
- MA with Coagulation disorders
- MA with lymphoma

Sociodemographics

- Sex
- Race
    - White
    - Black
    - Asian/PI
    - Native Amer
- Hispanic Ethnicity
- Employment Status (Incident) (Employed; Unemployed)

- Medicare coverage
  - Primary Traditional alone
  - Dual eligible
  - Medicare Advantage
  - Other
- Area Deprivation Index

5.4.2a Attach Conceptual Model

STrR_Conceptual-Model_Final_Oct-2025_508.pdf

5.4.3 Variable Distribution Across Measured Entities

See **STrR_5.4.3_Final_Oct 2025_508** PDF, attached to 5.4.3a

5.4.3a Attach Descriptive Statistics for Risk/Case-mix Variables

STrR_5.4.3_Final_Oct-2025_508.pdf

5.4.4 Risk/Case-Mix Adjustment Modeling and/or Stratification Results

See **STrR_5.4.4 and 5.4.4a_Final_Oct 2025_508** PDF, attached to 5.4.4a. The first 6 pages of the document address 5.4.4 and the 7th page addresses 5.4.4a

5.4.4a Attach Risk/Case-mix Adjustment Modeling and/or Stratification Specifications

STrR_5.4.4-and-5.4.4a_Final_Oct-2025_508.pdf

5.4.5 Calibration and Discrimination

To assess model performance, we evaluated discrimination using the C-statistics. The C-statistics quantifies the model's ability to discriminate between outcomes based on the included risk factors. Specifically, the STrR model is a recurrent event model, for which the C-statistics measures the concordance between the observed rates of recurrent events and the model-based predicted rates.

For the Fall 2025 maintenance submission, the C-statistic is 0.63, which indicates moderate model discrimination, reflecting the model's ability to distinguish high-risk from low-risk subjects.

Note: this text is also uploaded as an attachment to 5.4.5a since that is a required field.

5.4.5a Attach Calibration and Discrimination Testing Results

STrR_5.4.5a_Final_Oct-2025_508.pdf

5.4.6 Interpretation of Risk/Case-mix Factor Findings

See **STrR_5.4.6_Final_Oct 2025_508** PDF, attached to Section 7.1 Supplemental Attachment, for full response to this question

5.4.7 Final Approach to Address Risk Factors

Statistical risk adjustment model with risk factors

6.1.1 Current Status

In use

6.1.2 Current or Planned Use(s)

Public Reporting, Payment Program

6.1.3 Program Details

Name of the program and sponsor
Dialysis Facility Care Compare, Centers for Medicare and Medicaid Services
URL of the program
https://www.medicare.gov/care-compare
Purpose of the program

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

Geographic area and percentage of accountable entities and patients included

United States. All Medicare-certified dialysis facilities that are eligible for the measure and have at least 10 patient years at risk are included in the measure calculation for the program. For calendar year 2023, 7,268 U.S. dialysis facilities serving 473,742 patients would have had STrR results reported if the proposed version of the measure was in use.

Applicable level of analysis and care setting

Facility level, Dialysis Facilities

,
Name of the program and sponsor
ESRD QIP, Centers for Medicare and Medicaid Services
URL of the program
https://www.cms.gov/medicare/quality/end-stage-renal-disease-esrd-quality-incen...
Purpose of the program

The Centers for Medicare & Medicaid Services (CMS) administers the End-Stage Renal Disease Quality Incentive Program (ESRD QIP) to promote high-quality services in renal dialysis facilities. The first of its kind in Medicare, this program changes the way CMS pays for the treatment of patients who receive dialysis by linking a portion of payment directly to facilities' performance on quality of care measures. These types of programs are known as "pay-for-performance" or "value-

based purchasing" (VBP) programs.

Geographic area and percentage of accountable entities and patients included

United States. All Medicare-certified dialysis facilities that are eligible for the measure and have at least 10 patient years at risk are included in the measure calculation for the program. For calendar year 2023, 7,268 U.S. dialysis facilities serving 473,742 patients would have had STrR results reported if the proposed version of the measure was in use.

Applicable level of analysis and care setting

Facility level, Dialysis Facilities

,
Name of the program and sponsor
Dialysis Facility Reports, Centers for Medicare and Medicaid Services
URL of the program
https://data.cms.gov/quality-of-care/medicare-dialysis-facilities
Purpose of the program

The Dialysis Facility Reports (DFRs) are provided as a resource for characterizing selected aspects of clinical experience at this facility relative to other caregivers in this state, End Stage Renal Disease (ESRD) Network, and across the United States. Since these data could be useful in quality improvement and assurance activities, each state's surveying agency may utilize the DFRs as a resource during their survey and certification process. Measures included in the DFRs are updated annually and available to dialysis facilities to review and submit comments prior to their release to State Survey Agencies and Regional Offices in September of each year.

Geographic area and percentage of accountable entities and patients included

United States. All Medicare-certified dialysis facilities that are eligible for the measure and have at least 10 patient years at risk are included in the measure calculation for the program. For calendar year 2023, 7,268 U.S. dialysis facilities serving 473,742 patients would have had STrR results reported if the proposed version of the measure was in use.

Applicable level of analysis and care setting

Facility level, Dialysis Facilities

6.2.1 Actions of Measured Entities to Improve Performance

There are several actions that dialysis facilities can take to improve anemia management and avoid the need for red blood cell transfusion. These include:

- Use of an anemia manager and protocols to standardize use of ESA or HIF protease inhibitor administration and dosing.
- Optimize iron administration to aggressively treat iron deficiency
- Adjust frequency of monitoring hemoglobin (ie. Checking after hospitalization or other

absence from facility; checking more frequently if ESA is placed on hold)
- Evaluate patients with poor response to ESA for infection / inflammation.
- Collaborate with inpatient providers to follow guidelines and exercise a judicious use of red blood cell transfusions.

6.2.2 Feedback on Measure Performance

For DFCC, feedback can be provided any time through contacting the dialysisdata.org helpdesk. Preview periods allow for specific times for facilities review and comment on measure calculations, and provide an opportunity to request data suppression.

For the ESRD QIP, feedback can be provided any time through contacting the QIP helpdesk. Preview periods allow for specific times for facilities review and comment on measure calculations. Comments can also be submitted in response to the Notice of Proposed Rulemaking for each QIP calendar year.

DFCC: Comments received during DFCC preview periods tend to be technical in nature, asking for clarification on how the STrR is calculated for particular facilities, including questions about patient assignment and application of exclusion criteria.

QIP: Since the STrR was first proposed for the ESRD QIP commenters raised issues related to additional risk adjustment for SDS factors or clinical factors, and question whether the outcome of the measure (transfusions) were attributable to the dialysis facility. Both of these issues are addressed in this and prior successful submissions to the CBE.

6.2.3 Consideration of Measure Feedback

Based on the feedback received, we made the following changes:

- The measure has been modified from an approach that used a more extensive set of exclusion criteria for malignancies that might preclude the use of ESAs, to one of risk adjustment where these conditions have been added to the risk adjustment model and are no longer exclusion criteria.
- The measure has been modified to now adjust for GI bleeding. A panel of ICD-10 codes have been added to the risk adjustment model to account for GI bleeding, which can have a direct impact on transfusion risk and is generally believed to be outside the control of the dialysis facility.
- The denominator has been expanded to include patients with Medicare Advantage plans who had previously been excluded. Based on enrollment information from the Medicare Enrollment Database (EDB), the percentage of ESRD dialysis beneficiaries enrolled in Medicare Advantage (MA) has steadily increased over time. From 12% in 2010, the

proportion rose to 22% by 2020. Prior to 2020, there was an annual increase of approximately 1%. However, since 2021, the annual increase has been more than 5% The growth in ESRD beneficiaries joining MA plans carries significant implications for the metrics used to assess dialysis facility performance. Contrary to the data from Fee-For-Service (FFS) Medicare beneficiaries, MA outpatient encounters and administrative records have not been readily available for the purposes of analyzing facility quality, except for internal CMS use in risk adjustment and performance assessment.

6.2.4 Progress on Improvement

See **STrR_6.2.4_Final_Oct 2025_508** PDF, attached to Section 7.1 Supplemental Attachment, for full response to this question

6.2.5 Unexpected Findings

Patient denominator time at risk has fallen dramatically over the last several years, correlating with rapid increased uptake of Medicare Advantage insurance over the same interval. We saw these trends as negatively impacting both patients and facilities. For patients without Medicare FFS coverage, they were effectively excluded from the quality measure and consequently did not benefit from any postulated incentivization toward higher quality anemia management. Similarly, dialysis facilities were increasingly being judged on anemia management only for Medicare FFS patient outcomes. For those facilities in geographic areas with high MA uptake, results could have been biased by small sample size related to MA patient time at risk exclusion. The measure in this submission includes both FFS and ME time at risk and results in significantly larger number of patients, patient-years, and dialysis facilities included.

7.1 Supplemental Attachment

STrR_7.1-Supplemental-Attachment_Revised-Nov-2025.zip

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The measure developer is different from the measure steward

Yes

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Steward Organization

Centers for Medicare & Medicaid Services

Steward Organization URL

https://www.cms.gov/

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