NATIONAL QUALITY FORUM
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MEASURE WORKSHEET

This document summarizes the evaluation of the measure as it progresses through NQF's Consensus Development Process (CDP). The information submitted by measure developers/stewards is included after the Brief Measure Information, Preliminary Analysis, and Pre-meeting Public and Member Comments sections.

To navigate the links in the worksheet: Ctrl + click link to go to the link; ALT + LEFT ARROW to return

Brief Measure Information

NQF #: 3696

Measure Title: Standardized Modality Switch Ratio for Incident Dialysis Patients (SMoSR)

Measure Steward: Centers for Medicare & Medicaid Services

Brief Description of Measure: The standardized modality switch ratio (SMoSR) is defined to be the ratio of the number of observed modality switches (from in-center to home dialysis—peritoneal or home hemodialysis) that occur for adult incident ESRD dialysis patients treated at a particular facility, to the number of modality switches (from in-center to home dialysis—peritoneal or home hemodialysis) that would be expected given the characteristics of the dialysis facility's patients and the national norm for dialysis facilities. The measure includes only the first durable switch that is defined as lasting 30 continuous days or longer.

The SMoSR estimates the relative switch rate (from in-center to home dialysis) for a facility, as compared to the national switch rate. Qualitatively, the degree to which the facility's SMoSR varies from 1.00 is the degree to which it exceeds (> 1.00) or is below (< 1.00) the national modality switch rates for patients with the same characteristics as those in the facility. Ratios greater than 1.00 indicate better than expected performance while ratios <1.00 indicate worse than expected performance.

When used for public reporting, the measure calculation will be restricted to facilities with at least one expected modality switch in the reporting year. This restriction is required to ensure patients cannot be identified due to small cell size.

Developer Rationale: Home dialysis rates remain low in the United States compared with many other countries (as of 2019, 10.8% PD, 1.8% HHD). This measure will allow one to compare the effectiveness of facility modality education and/or effective utilization of home dialysis modalities. This will be a facility outcome metric for comparison across the US including longitudinal monitoring. It is patient centered in that it is intended to facilitate on-going education that may result in patients choosing a home modality, particularly if there was no pre-dialysis modality education provided. The quality of care will be improved by better alignment between patients' goals and values and their dialysis modality. The focus is on incident patients since most modality changes occur during the first year and likely reflect robust education, effective presentation, and facilitation by the dialysis unit.

Numerator Statement: Observed number of switches from in-center hemodialysis to a home dialysis modality (peritoneal dialysis or home hemodialysis) among eligible patients at the facility during the time period.

Denominator Statement: Expected number of switches from in-center hemodialysis to a home dialysis modality (peritoneal dialysis or home hemodialysis) among eligible patients at the facility during the time period, given the national average of modality switches, and patient case-mix at the facility.

Denominator Exclusions: The following exclusions are applied to the denominator:

- Patient's time at risk under hospice care
- Patient's time at risk when in a nursing home and on home hemodialysis
- Pediatric patients (less than 18 years of age)
- Patients with no CMS-2728 Medical Evidence Form (i.e., AKI patients on dialysis but not designated as ESRD)

Patients who are attributed to clinics with fewer than 1 expected modality switch are not excluded from the measure. All *patients* who meet the denominator inclusion criteria are included and used to model a given facilities expected switch rate to home dialysis. If that switch rate is <1, then the *facility* is excluded from reporting outcomes.

Measure Type: Outcome

Data Source: Registry Data, Claims

Level of Analysis: Facility

Preliminary Analysis: New Measure

Criteria 1: Importance to Measure and Report

1a. Evidence

1a. Evidence. The evidence requirements for a ***health outcome*** measure include providing empirical data that demonstrate a relationship between the outcome and at least one healthcare structure, process, intervention, or service; if these data not available, data demonstrating wide variation in performance, assuming the data are from a robust number of providers and results are not subject to systematic bias. For measures derived from patient report, evidence also should demonstrate that the target population values the measured outcome, process, or structure and finds it meaningful.

The developer provides the following description for this measure:

- This is a new outcome measure at the group/practice level that compares observed modality switches (from in-center to home dialysis—peritoneal or home hemodialysis) that occur for adult incident ESRD dialysis patients treated at a particular facility, to the number of modality switches (from in-center to home dialysis—peritoneal or home hemodialysis) that would be expected given the characteristics of the dialysis facility's patients and the national norm for dialysis facilities.
- The developer provides a logic model that identifies patients who were initiated on in-center dialysis and have switched to home dialysis due to facilities providing effective education regarding home dialysis which allows patients to make informed decisions and help care management align with their goals of care and values.

Summary:

- The developer provides the following evidence for the Standardized Modality Switch Ratio for Incident Dialysis Patients (SMoSR) measure:
    - Evidence provided includes information on the impact of home dialysis, a mismatch between patient's stated preferences for dialysis modality and their actual dialysis modality, and factors impacting the uptake of home hemodialysis modalities.

- The developer cites evidence from observational studies in the United States (US) and other countries outside the US such as Canada, several European countries, Australia, and New Zealand. The developer further states that there are few randomized control trials that examine the relationship between dialysis modalities and outcomes.
- According to the developer, some studies found that clinical, operational, economic, and patient factors have been identified as barriers to uptake of home dialysis modalities. Factors include lack of physician competency in prescribing home dialysis modalities, lack of clinician training, lack of sufficient housing or storage space for dialysis supplies, or adequate education. Low rates of home dialysis are associated with both patient and facility level factors such as race, sex, age, comorbidities, small facility size, and physician/nurse experience.
- The developer noted that studies that examined the role and impact of education on home modality uptake showed that approximately 30% of chronic dialysis patients have reported their modality selection was not really their choice or did not feel as though they made an informed choice, and that this percentage is higher among in-center hemodialysis (ICHD) patients
- The developer noted that some studies have shown a survival advantage associated with peritoneal dialysis (PD) as an initial modality however evidence is mixed about the longer-term outcomes and survival benefit for PD versus in-center hemodialysis.
- The developer concluded that the studies support the construct of the measure which is an indicator of successful education by the facility to facilitate a decision to switch to a home modality after a patient starts on in-center hemodialysis.

Question for the Committee:

- *Is a relationship demonstrated between SMoSR and at least one healthcare structure, process, intervention or service?*

Guidance from the Evidence Algorithm

Outcome measure that assesses performance on a health outcome (Box 1) à the relationship between the measured health outcome and at least one health action is demonstrated by empirical data (Box 2) à Pass

Preliminary rating for evidence: ☒ **Pass** ☐ **No Pass**

1b. Gap in Care/Opportunity for Improvement and Disparities

1b. Performance Gap. The performance gap requirements include demonstrating quality problems and opportunity for improvement.

- The developer presented an analysis of descriptive statistics for the standardized modality switch ratio from 2016-2019.
    - Specifically, the developers evaluated all Medicare-certified dialysis facilities (n=6,039) that treated incident patients (n=316,382) that had at least one expected patient modality switch in the reporting years after applying all exclusion criteria.
    - The mean SMoSR was 1.07, the first quartile performance was 0.37 and the third quartile performance was 1.52 demonstrating a wide range of provider performance on this measure.
    - 933 facilities had a mean SMoSR of zero and were grouped into the first decile. Decile 2's mean SMoSR was 0.21 and the 10th decile's mean SMoSR was 3.26.

Disparities

- The developer presented a hazard of a modality switch by race, ethnicity, sex, employment status, and Medicare dual eligibility using data from 2016-2019.
    - The observed rate for black, Native American and Asian/Pacific Islander patients had a lower hazard of a modality switch (0.59, 0.67 and 0.86, respectively) compared to white patients.
    - Hispanic patients had lower hazard of a modality switch (HR = 0.67) compared to non-Hispanic patients. The hazards of modality switches were not statistically significant between male and female patients (HR=0.99, 95% CI: 0.96, 1.02).
    - Patients employed 6 months prior to the onset of ESRD had a higher hazard of modality switch (HR=2.00) than patients that were unemployed. Medicare dual eligible patients had a lower hazard of a modality switch (HR=0.57) than other patients.

Questions for the Committee:

- *Is there a gap in care that warrants a national performance measure?*

Preliminary rating for opportunity for improvement: ☐ **High** ☒ **Moderate** ☐ **Low** ☐ **Insufficient**

Committee Pre-evaluation Comments:

1a. Evidence

- Developer provides evidence to support the outcome of switching modality could align with patient choice. also provides comparison to other countries which demonstrates evidence to focus on measurement in this area
- Evidence provided focuses on barriers to home dialysis, modality education and preference, and clinical outcomes.
- Evidence remains moderately strong
- The evidence presented provides a rationale for waitlisting as an outcome, but is tangential to the intermediate outcome being measured. The developer indicates the basic premise of the measure is that patients who consent to changing their treatment modality from in-center to home do so as a result of iterative education efforts and effective decision support by the dialysis facility, which can help patients select a modality that is best aligned with their personal goals and values. It's unclear, however, how the developer arrived at modality switch rates as a valid proxy for proper patient education. Certainly the measure will incentivize switching in-center patients to home dialysis, but there is no mechanism for the measure to discern whether such conversions are the result of the "iterative education efforts and effective decision support" that the developer envisions. The measure offers no insight whatsoever into degree or quality of education and training the patient received in preparation for the switch, and implementation of the measure may even inadvertently infringe on patient choice. Any home dialysis-related measure, particularly when tied to financial incentives, must be approached with considerable caution to ensure that patients who should not or do not want to receive home dialysis are not pressured into selecting a home modality. Additional concerns with the measure include the following: The measure addresses only a small subset of patients—incident patients who switched from in-center to home dialysis within the first year of treatment; the measure will thus likely do little to "move the marker" on overall home dialysis utilization within facilities and across dialysis organizations. There is also significant room for improvement in home dialysis utilization in prevalent patients; with the exclusion of this population, the measure misses a significant

opportunity to drive performance improvement. Because the measure only gives "credit" for incident patients specifically who switch from in-center to a home modality, there is considerable risk that implementation of the SMoSR in a penalty-based program would create a perverse, paradoxical incentive to start new patients on in-center dialysis so as to allow for a subsequent modality "switch" to home, for which credit could be received.

- Evidence provided includes information on the impact of home dialysis a mismatch between patients stated preferences for dialysis modality and their actual dialysis modality and the factors impacting the uptake of home hemodialysis modalities.
- Acceptable evidence focused on factors influencing decision making for dialysis modality and role of provided education/information in fostering decisions to do home dialysis
- Home dialysis numbers are low in the US for adults compared to other countries, suggesting underutilization. This measure focuses on the ratio of switching from in center HD to home modality in the 1st year to encourage education to the patients about home dialysis options.
- Utilization of home therapies is associated with patient education and overall utilization is lower than other countries. The data are mostly observational. A randomized trial of VA patients to answer the question as to comprehensive education is estimated to complete in July 2024. The impact of AAKH and the KCC models on home therapy selection are largely outside the time frame of the data presented.
- I am not aware of other studies.
- Evidence low -- also not clear if there is a relationship demonstrated between the SMoSR and at least one healthcare structure, process, intervention or service (as is required for a new health outcome measure). Changes in dialysis modality are an important consideration for dialysis patients and moving from in center to home dialysis is often viewed as an improvement in care. SMoSR (a facility level measure), is an interesting measure based on observational data from various Countries and the US. The observations have not yet been substantiated by any controlled trials or measurements. The premise of the measure suggests that patients change their treatment modality from in-center to home in direct relationship to programed educational efforts and effective decision-support efforts provided by the dialysis facility. The measure offers no guidance or benchmarks as to the type, format, quality, frequency or effectiveness of any educational efforts, accomplished prior to the switch. Without controlled studies it is difficult to presume that modality switches are due to, or can serve as a proxy for, effective educational efforts and clinical support on the part of the dialysis provider. An immediate concern is the lack of a mechanism, or effective measure, by which to determine if a modality conversion occurred due to "effective educational efforts" as envisioned, or if the switch occurred because facilities are being "encouraged to switch patients." As developed, the measure seems to assume that modality switches from in-center to home are simply related to educational efforts, without an assessment as to the effectiveness of the education. In this context, patients may be urged to initiate home dialysis despite an absence of adequate training and education. Thus, the measure itself may "drive the shift to home dialysis," which , in turn, may have unintended consequences.
- Increased home dialysis is clearly beneficial. However, I have concerns that this measure might facilitate avoiding remedies addressing the underlying cause of inadequate utilization of home modalities (poor care and education of people with advanced CKD) by promoting switch after initiation.
- Pass
- True
- The evidence to support higher home dialysis use is reasonable, but I do not find evidence to support switching from in-center to home as a reasonable metric. Note: in practices where initial use of home

therapies is high, few candidates remain in the on-center setting. Thus, a practitioner who is a major home user can have a very low rating for switches.

- No issues with evidence.
- The developer has a described a new measure- Standardized modality switch ratio as measure to compare the effectiveness of facility education and /or effective utilization of home dialysis modalities. Home dialysis whether in the form of peritoneal or home hemo dialysis appears to have a survival advantage and thus the need for a measure as an indicator of the facility ability to educate and facilitate patient's decision to switch to a home modality. There is a relationship between the measure and outcome for the patient.
- The data supports better outcomes with home dialysis.

1b. Gap in Care/Opportunity for Improvement and Disparities

- Disparities presented were compelling. Gap does exist with this focus area.
- Examined 6,039 facilities treating 316,382 incident patients: SMoSR Q1 0.37 and Q3 1.52, with variation in performance across deciles. Data from 2016-2019 showed differences in performance based on race, ethnicity, sex, employment, and DE.
- Gap was identified amongst providers and amongst patient demographics
- Unclear. Gaps in both provider performance and between racial and ethnic groups is presented; however, it's unclear how "expected" modality switches were determined; request clarification from the developer.
- Developer presented a hazard of a modality switch by race, ethnicity, sex, employment status and Medicare dual eligibility using data from 2016 to 2019. Rate for blacks, native American and Asian pacific islander patients had a lower hazard of a modality switch 0.59, 0.67 and 0.86 compared to whites. Hispanic patients had lower hazard of a modality switch 0.67 compared to non-Hispanic patients. Modality switches were not statistically significant between male and female patients. Pts employed 6 months prior to the onset of ESRD had a higher hazard of modality switch than patients that were unemployed. Medicare dual eligible patients had a lower hazard of a modality switch than other patients. Moderate rating for improvement.
- Performance data provided and showed wide range of performance with significant performance gap from "desired" and notable disparities
- Shows a gap for patients who are not white, those who are Hispanic and those with lower socioeconomic status.
- Yes. 4.7% of facilities had a worse than expected switch rate. Older age, Black race, API, NA, AN, Hispanic, dual eligible, and zip code in ADI correlated to HR<1 for switch. But these were days reportedly adjusted for SES/SD. We're column headings mislabeled?
- I'm not sure all of the data was provided.
- Moderate using one modality switch as the starting point and ignoring the first decile (since facilities with no home were included in the first level) a moderate difference between facilities is present. Of note, however, are that data jump from 1.97 (9th decile) to 3.26 (SD 1.12) among the 10th decile. This may warrant further evaluation regarding the frequency of changes among that decile. 88% of facilities performed "as expected" suggesting that the overall gap in performance is not large
- Performance gap in utilization of home modalities.
- Moderate gap
- True
- There is a gap for home use, but I find no evidence for a gap in switching.
- Performance gaps and disparities do exist.
- Current performance gap was provided and showed a gap for race and employment status.

- There is a gap: more than 10% of facilities are underperforming facilities.

Criteria 2: Scientific Acceptability of Measure Properties

Complex measure evaluated by Scientific Methods Panel? ☒ **Yes** ☐ **No**

Evaluators: Dave Nerenz, Matt Austin, Zhenqiu Lin, Joseph Kunisch, Patrick Romano, Susan White, Daniel Deutscher, John Bott, Ron Walters, Jennifer Perloff, Eugene Nuccio, Joseph Hyder (Combined Methods Panel Review)

- The SMP Passed on Reliability with a score of: H-0; M-6; L-2; I-0
- The SMP Passed on Validity with a score of: H-1; M-5; L-2; I-0

2a. Reliability: Specifications and Testing

2a1. Specifications requires the measure, as specified, to produce consistent (reliable) and credible (valid) results about the quality of care when implemented.

2a2. Reliability testing demonstrates if the measure data elements are repeatable, producing the same results a high proportion of the time when assessed in the same population in the same time period and/or that the measure score is precise enough to distinguish differences in performance across providers.

Specifications:

- Measure specifications are clear and precise.

Reliability Testing:

- Reliability testing conducted at the Accountable-Entity Level:
    - Testing was conducted using the inter-unit reliability (IUR) with a bootstrap approach. This approach utilizes a resampling procedure to estimate the within facility variation that cannot be directly estimated by ANOVA. The developer also calculated a profile inter-unit reliability (PIUR). This approach assesses the measure's ability to consistently flag extreme providers.
        - The developer calculated a IUR value of 0.605 for the measure, which indicates that over 60% of the variation in the measure can be attributed to the between-facility differences and less than 40% to the within-facility variation. The PIUR is 0.606.
        - The developer notes that this IUR value is moderate and indicates that the measure can reliably detect differences in performance scores across facilities; the PIUR demonstrates a similar ability to flag outliers.

SMP Summary:

- Reliability testing passed the SMP's preliminary review and therefore was not discussed at the SMP meeting. The SMP did not report any significant concerns regarding reliability during their preliminary review.

Questions for the Committee regarding reliability:

- *Do you have any concerns that the measure cannot be consistently implemented (i.e., are measure specifications adequate)?*
- *The Scientific Methods Panel is satisfied with the reliability testing for the measure. Does the Committee think there is a need to discuss and/or vote on reliability?*

Preliminary rating for reliability: ☐ **High** ☒ **Moderate** ☐ **Low** ☐ **Insufficient**

2b. Validity: Validity testing; Exclusions; Risk-Adjustment; Meaningful Differences; Comparability; Missing Data

2b2. Validity testing should demonstrate the measure data elements are correct and/or the measure score correctly reflects the quality of care provided, adequately identifying differences in quality.

2b2-2b6. Potential threats to validity should be assessed/addressed.

Validity Testing

- Validity testing conducted at the Accountable Entity Level:
    - The developer used multiple approaches to test validity of the measure including:
        - The first was using Spearman's rho Correlations with Quality Outcome Performance Measures:
            - Standardized Mortality Ratio (SMR)
                - As the developer hypothesized, the association between this measure and SMR was very weak. Spearman's rho was 0.030 with a p-value of 0.038.
            - First-Year Standardized Mortality Ratio (FYSMR)
                - As the developer hypothesized, the association between this measure and FYSMR was very weak. Spearman's rho was -0.030 with a p-value of 0.022.
            - Standardized Hospitalization Ratio (SHR)
                - As the developer hypothesized, the association between this measure and SHR was very weak. Spearman's rho was -0.060 with a p-value of less than 0.0001.
            - Standardized Waitlist Ratio-Incident Dialysis Patients (SWR)
                - This measure is associated with the Standardized Waitlist Ratio-Incident Dialysis Patients (SWR) (Spearman's rho=0.12, p-value= less than .0001), in the developer's expected direction.
                - The developer notes that facilities that do well facilitating education on transplant that results in patient waitlisting within the first year, are also performing well providing effective education on home dialysis that results in switches from in-center to home dialysis within the first year.
                - The developer also found that this measure and Standardized Waitlist Ratio-Incident Dialysis Patients (SWR) had a positive Gamma coefficient of 0.29 and was statistically significant ($p<0.0001$) indicating that facilities that perform significantly better helping patients switch to home dialysis also do significantly better in helping patients in the referral and waitlisting process for transplant.
            - ICH-CAHPS "Providing information to patients"
                - The developer found that the facilities with a better performance on this measure have a higher ICH-CAHPS score for providing information to patients (Pearson's r = 0.191)
            - The percentage of home dialysis patients at the facility
                - The developer found moderate correlation between the percentage of home dialysis patients and performance on this measure (Pearson's r = 0.398). This is the hypothesized direction of the correlation. The developer

used the percentage of home dialysis patients at the facility as a proxy for more effective modality education.

- The developer also presented a two-part continuous model for the same outcome of percentage home dialysis patients. The logistic regression part of the model asserts that each unit increase in this measure is associated with a 30 percent decrease in odds of observing a facility with zero home-dialysis patients (p-value < 0.001).
- The linear regression component of the model indicates that for facilities with non-zero number of home dialysis patients, the proportion of home dialysis patients is positively associated with the SMoSR (beta coefficient=2.9, p<.0001)
- Based on these results, the developer states that facilities providing more effective modality switch education have higher SMoSRs.

Exclusions

- To evaluate exclusions, the developer calculated the number and percent of patient-time at risk and unique patients for the current measure (with exclusions) and compared that to the measure without exclusions. The measure exclusions include: (1) patient's time at risk under hospice, (2) patient's time at risk when in a nursing home and on home hemodialysis, (3) pediatric patients (less than 18 years of age), and (4) patients with no CMS-2728 Medical Evidence From.
- For two of the exclusions, the developer provided the number of either patient-time or unique patients before and after applying the exclusion. In both presentations of the numbers, the exclusions led to a 0.17 percent and 0.732 percent decline in patient years for nursing home and hospice care exclusions, respectively.
- The developer noted that the facility level performance rankings are minimally affected (88 percent as expected before and after exclusions). The developer also noted that the measure with and without the hospice (r=0.999) and nursing home (r=0.984) exclusions were highly correlated.
- The developer stated these exclusions are important because the number of hospice or nursing patients are not evenly distributed across facilities.

Risk-Adjustment

- The developer conducted a statistical risk model with 18 variables including age, diabetes as cause of ESRD, BMI at ESRD incidence (4 categories), comorbidities at ESRD incidence (14 categories) and calendar year.
- The risk model is a two stage Cox model with the first stage being a patient model stratified by facility to avoid bias caused by different covariate distributions across facilities. The second stage model is a linear model using the estimates of the first stage model to fit an unstratified Cox model. The fitted stage 2 model computes the expected probability of modality switch for each patient based on adjusters and number of days assigned to a facility.
- The C-statistic was 0.674, suggesting good predictive ability of the risk model.
- Decile plots show that the risk factors in the model are discriminating well between patients. There is good separation among all 10 deciles and the ordering is as predicted by the model.
- While several SDS factors (race, Hispanic ethnicity, female sex, and other SES factors) were associated with decreased uptake of home dialysis in the patient-level analyses conducted by the developer, these factors were not included in the final risk adjusted model for SMoSR. The developer states that though the factors

are associated with a decreased uptake in home dialysis in the patient-level analysis, the impact is attenuated at the facility-level analysis. Meaning that 95.2 percent of facilities performance category would not change with or without adjustment of these factors.

Meaningful Differences

- Facilities were classified into three categories: 'As Expected', 'Better than Expected', or 'Worse than Expected'. The facilities were split into these categories based on if observed and expected values are statistically different at the 5% level. The developer reported the proportion of facilities with statistically significant differences. They calculated the p-value using a Poisson approximation.
- After adjusting for case mix and expected variation using the Cox model, 7.7 percent of facilities performed better than expected, 4.3 percent performed worse than expected and 88 percent performed as expected. Over the period 2016-2019, the model was able to detect 12 percent of facilities with performance either significantly above or below expectations.
- The developer stated that these results suggest that the measure is able to detect statistically significant differences in performance, specifically facilities that do much better or worse than the national average.

Missing Data

- All ESRD patients are required to have a CMS form 2728 to be included in the measure because the form certifies that the patient has ESRD. However, some patients are missing the primary case of ESRD or BMI from the CMS 2728.
- The developer states that missing data occurs rarely. Patients missing the primary cause of ESRD represented 0.02 percent of patients and missing BMI were 0.31 percent of all patients.
- The developer states that because such a small amount of missing data is present, the impact is negligible on the performance scores and is unlikely to be a source of bias.

Comparability

- The measure only uses one set of specifications for this measure.

SMP Summary:

- Validity testing passed the SMP's preliminary review and therefore was not discussed at the SMP meeting.
- During their preliminary review, the SMP did note some concerns with the risk adjustment model. Specifically, they took issue with the developer leaving out some social or demographic risk factors as including them would improve the model's fit. However, the SMP agreed the measure is valid and that inclusion or exclusion of certain social risk factors is an issue for the Standing Committee to discuss.

Questions for the Committee regarding validity:

- *Do you have any concerns regarding the validity of the measure (e.g., exclusions, risk-adjustment approach, etc.)?*
- *Does the Standing Committee have any concerns that all measure exclusions were not tested?*
- *Does the Standing Committee have any concerns about the risk adjustment model?*
- *The Scientific Methods Panel is satisfied with the validity analyses for the measure. Does the Committee think there is a need to discuss and/or vote on validity?*

Preliminary rating for validity: ☐ **High** ☒ **Moderate** ☐ **Low** ☐ **Insufficient**

Committee Pre-evaluation Comments:

2a1. Reliability – Specifications

- No concerns noted with the specifications.
- Clarify if requirement for 30 continuous days of home dialysis includes training days.
- No concerns
- Data elements are clearly defined; again, however, additional information on how "expected" modality switches were determined is necessary to fully assess the measure logic and calculation algorithm.
- Testing was conducted using the IUR with a bootstrap approach. This approach utilizes a resampling procedure to estimate the within facility variation that cannot be directly estimated by ANOVA. The developer calculated a IUR which assessed the measures ability to consistently flag extreme providers. IUR value of 0.605 for the measure which indicates that over 60 percent of the variation in the measure can be attributed to the between facility differences with less than 40% to the within facility variation. IUR value is moderate which indicates that the measure can reliably detect differences in performance scores across facilities, the PIUR demonstrates a similar ability to flag outliers. Reliability is rated moderate.
- Specifications seem clear and no concerns re: consistent implementation
- No concerns
- I am curious why the switch has to be durable if the point is that the patient received education and agreed to the switch. Units that had less than 90 days to educate a patient might be at a disadvantage.
- I would need more information.
- The IUR is moderate at 0.605. A value of 0.7 is typically used to indicate a "good " model
- Data elements clear
- Moderate reliability
- True
- No concerns
- How is self-care used or defined in this measure? Was Transitional Care accounted for? If so, how?
- Data elements are clear
- None

2a2. Reliability – Testing

- 60% variation in the measure attributed to the between facility differences. less than 40% variation within facility
- Data for 2016-2019: IUR 0.605, PIUR 0.606. Is this for a 3-year measurement period with one year of follow-up? Given IUR, would be helpful to understand performance in smaller facilities.
- No concerns
- Yes. While the overall IUR across all facilities is acceptable at 0.605, stratification of reliability scores by provider size was not detailed. Because of this, it's impossible to determine how widely reliability varies across the spectrum of provider/group sizes. As has often been the case with other CMS measures, reliability for small providers might be substantially lower than the overall IUR, effectively rendering the metric meaningless for use in performance measurement in this group. Request CMS provide data demonstrating reliability for all providers by detailing IURs by provider/group size.
- No concerns about the reliability of the measure
- IUR calculations with moderate ensuing reliability
- No concerns

- By IUR, measure is moderately likely to demonstrate true inter facility differences.
- I'm not sure all of the data was provided.
- The IUR is NOT robust. It is confusing that patients from facilities without a home program are included in the measure.
- No
- Moderate reliability
- Appropriate
- Yes, no good testing provided
- No concerns
- I have no concerns about the reliability of the measure.
- No

2b1. Validity – Testing

- SMP addresses some concerns but developer is able to respond or explain rational.
- Very weak correlation with SMR, FYSMR, and SHR. SMoSR and SWR Spearman's rho 0.12. SMoSR and ICH CAHPS Pearson's r=0.191.
- No concern
- Correlations with other outcomes measures were very weak and not statistically significant in most cases.
- No concerns about the testing results. Done at the Accountable Entity Level
- Validity testing acceptable at low moderate level
- No concerns
- There is no assessment of capacity for home training at a time when staffing is a major issue
- I'm not sure all of the data was provided.
- The validity test was performed by comparing this measure to other measures with which the developer expected to find NO Correlation. Other than "preexisting home dialysis patients already at the facility," The Standard Transplant wait list ratio was the only significantly positively correlated measure. The developer noted: Facilities that do well facilitating education on transplant that result in patients wait listing within the first year, are also performing well providing effective education on home dialysis that results in switches from in-center to home dialysis in the first year. There is no evidence presented to support this statement as a test of measure validity.
- No
- No concerns
- Appropriate
- Yes - uncertain validity
- Low to moderate validity
- I have no concerns about the testing results.
- None

2b2-3. Threats to Validity (Exclusions, Risk Adjustment)

- If including race, Hispanic ethnicity, female sex and other SES factors did not impact facilities performance categories when included in risk adjustment why not include rather than exclude?
- Exclusions: hospice care, NH residence on HHD, <18 years of age, absence of CMS 2728 (proxy for AKI). Model includes age, BMI, cause of ESRD, incident ESRD comorbidities (CMS 2728), incident calendar year. C statistic 0.674. Recommend committee discuss exclusions and risk-adjustment.

- Exclusion includes nursing home, hospice. How about patients who are living solo or without support at home? These individuals may be unsafe for home modalities but do not seem to be excluded from the denominator
- No concerns with exclusions. The risk model appears to fit well, with a c-statistic of 0.674; however, the SMP's concerns on the inclusion of social risk variables in the final model are noted. A discussion among Standing Committee members would be helpful on this issue.
- SMP did note some concerns with the risk adjustment model. They took issue with the developer leaving out some social or demographic risk factors as including them would improve the models fit. SMP agreed measure is valid and that inclusion of certain social risk factors is an issue for the standing committee to discuss.
- No inappropriate exclusions
- I think that demographic and socioeconomic factors should be included in the risk adjustment strategy
- I am not sure the data permits the inference that it is predominantly education that accounts for influence of SDS/SES factors on switch
- I'm not sure all of the data was provided.
- Risk adjustment for social and demographic risk factors were excluded from the adjusted model. The developer noted that adjustment for these risk factors moved bidirectionally depending upon the risk factor under consideration. Based on the impact that socio and demographic factors might have in determining suitability for a home dialysis modality, it would seem that these factors should be included, especially since they may not be evenly distributed across facilities
- Would this measure penalize providers who successful in promoting Optimal Starts?
- Exclusions are consistent. Risk adjustments appropriately developed.
- True
- Are patients who choose not to use home therapies excluded? If not, this provides a substantial risk of harm of coercion.
- Same as above. Possibly consider adding additional social risk factors. Modality education - should this be considered as education varies
- Exclusions are appropriate.
- There should be risk adjustment for SES

2b4-2b7. Threats to Validity (Statistically Significant Differences, Multiple Data Sources, Missing Data)

- Small amount of missing data. Meaningful differences among facilities in performance is able to be detected.
- Minimal missing information (<1% cause of ESRD, <1% BMI)
- Minimal concern
- Scores differentiated as "as expected," "better than expected," and "worse than expected." No concerns with approach. No concerns around missing data.
- Developer used multiple approaches to test validity of the measure including: using Spearman's rho correlations with quality outcome performance measures. Association between SMR was very weak 0.30 p value of 0.038. FYSMR association between this measure was very weak 0.030 with a p value of 0.022. SHR was also very weak p value of 0.0001. Exclusions are important because the number of hospice or nursing patients are not evenly distributed across facilities. Meaningful differences were where facilities were classified into 3 categories--as expected, better than expected or worse than expected. Adjusted for case mix and expected variation using the Cox model 7.7 percent of facilities performed better than expected 4.3 performed worse than expected and 88 percent performed as expected. From 2016 - 2019 the model was able to detect 12 percent of facilities with performance either significant differences in performance specifically facilities that do much better or worse than

national average. CMS form 2728 where some patients are missing primary cause of ESRD or BMI…not a threat to validity.

- No notable threats to validity
- No concerns
- Honoring patient choice is interpreted as a quality outcome (patient centered care, access to care). But not choosing home therapy may reflect patient choice. So this is really a measure about adequacy of education and the Spearman correlation to SWR of 0.12 and concordance data are offered as evidence. Units with more PD patients had more switches. SNF HHD and hospice exclusions depend on Medicare as payment source but these have minimal impact.
- I'm not sure all of the data was provided.
- 2b4. Based on the data presented 88% of facilities are rated "as expected" and a total of 4.3% are rated as low outliers. This, together with the modest C score raises the question as to the validity or strength of the measure as a quality improvement application
- Would this measure penalize providers who successful in promoting Optimal Starts?
- Only moderate threat to validity due to comparability of performance scores.
- Yes
- I do not find that measuring switches relates to meaningful differences in quality
- Self care and transitional care = should these be included?
- I have no concerns about threats to validity
- It is not clear that 30 days of switch is adequate to derive benefits. If the patient switches back to in-center dialysis on day 31, it may do more harm than good

Criterion 3. Feasibility

3. Feasibility is the extent to which the specifications including measure logic, require data that are readily available or could be captured without undue burden and can be implemented for performance measurement.

- The developer states that the data elements are generated or collected and used by healthcare personnel during the provision of care. Further, the data elements are coded by someone other than the person obtaining original information.
- The developer states that the measure relies on data elements that are defined in a combination of electronic sources.

Questions for the Committee:

- *Are the required data elements routinely generated and used during care delivery?*
- *Are the required data elements available in electronic form, e.g., EHR or other electronic sources?*
- *Is the data collection strategy ready to be put into operational use?*

Preliminary rating for feasibility: ☒ **High** ☐ **Moderate** ☐ **Low** ☐ **Insufficient**

Committee Pre-evaluation Comments:

3. Feasibility

- No concerns.

- No concerns about feasibility
- Generally appear feasible
- No concerns with feasibility for this measure.
- Data elements are generated or collected and used by healthcare personnel during the provision of care. Data elements are coded elements that are defined in a combination of electronic sources.
- No significant concerns
- No concerns
- None
- I'm not sure all of the data was provided.
- Feasibility high
- Elements routinely generated
- High rate of feasibility
- Appropriate
- No concerns
- No issues
- Data elements are routinely generated and are found in electronic sources.
- None

Criterion 4: Use and Usability

4a. Use (4a1. Accountability and Transparency; 4a2. Feedback on measure)

4a. Use evaluates the extent to which audiences (e.g., consumers, purchasers, providers, policymakers) use or could use performance results for both accountability and performance improvement activities.

4a.1. Accountability and Transparency. Performance results are used in at least one accountability application within three years after initial endorsement and are publicly reported within six years after initial endorsement (or the data on performance results are available). If not in use at the time of initial endorsement, then a credible plan for implementation within the specified timeframes is provided.

Current uses of the measure

Publicly reported?	☐	Yes	☒	No		
Current use in an accountability program?	☐	Yes	☒	No	☐	UNCLEAR
Planned use in an accountability program?	☒	Yes	☐	No	☐	NA

Accountability program details

- The developer plans to submit this for use in payment programs such as the ESRD Quality Incentive Program or the Dialysis Facility Care Compare website.

4a.2. Feedback on the measure by those being measured or others. Three criteria demonstrate feedback: 1) those being measured have been given performance results or data, as well as assistance with interpreting the measure results and data; 2) those being measured and other users have been given an opportunity to provide feedback on the measure performance or implementation; 3) this feedback has been considered when changes are incorporated into the measure

Feedback on the measure by those being measured or others

- This is a new measure; therefore, no feedback has been obtained by those being measured or measure users. However, during the development phase the developers convened a multistakeholder group which noted support for this measure.
    - The TEP specifically stated that home dialysis is underutilized and that a quality measure would be useful to patients, providers, and other stakeholders.
    - The TEP also supported the basic construct of the measure and agreed that the measure should be considered for modification over time as new information becomes available.
- The developer noted that they presented a draft version of the measure for discussion by the TEP.
    - The TEP made several recommendations for changes to the measure specifications such as the definition of durable switch which were implemented in the final measure.

***Questions for the Committee**:*

- *How have (or can) the performance results be used to further the goal of high-quality, efficient healthcare?*
- *How has the measure been vetted in real-world settings by those being measured or others?*

Preliminary rating for Use: ☒ **Pass** ☐ **No Pass**

4b. Usability (4b1. Improvement; 4b2. Benefits of measure)

4b. Usability evaluates the extent to which audiences (e.g., consumers, purchasers, providers, policymakers) use or could use performance results for both accountability and performance improvement activities.

4b.1 Improvement. Progress toward achieving the goal of high-quality, efficient healthcare for individuals or populations is demonstrated.

Improvement results

- The measure is not yet implemented in a public reporting program, so improvement could not be evaluated. CMS currently anticipates implementation of this measure. Once implemented, facility performance on the measure can be evaluated to determine if the measure has supported and detected quality improvement in switch rates among the target population.

4b2. Benefits vs. harms. Benefits of the performance measure in facilitating progress toward achieving high-quality, efficient healthcare for individuals or populations outweigh evidence of unintended negative consequences to individuals or populations (if such evidence exists).

Unexpected findings (positive or negative) during implementation

- Developer did not report any unexpected findings as the measure is not implemented yet.

Potential harms

- Developer did not report any potential harms as the measure is not implemented yet.

***Questions for the Committee**:*

- *How can the performance results be used to further the goal of high-quality, efficient healthcare?*
- *Do the benefits of the measure outweigh any potential unintended consequences?*

Preliminary rating for Usability and use: ☐ **High** ☒ **Moderate** ☐ **Low** ☐ **Insufficient**

Committee Pre-evaluation Comments:

4a. Use

- New measure. Not publicly reported or in use. Plans to use in the future for Dialysis Facility Care Compare or ESRD Quality Incentive program
- Planned for future use
- No issues
- This is a new measure, not yet being publicly reported. It is intended for use in publicly reported programs, thus results will be disclosed and available to the broader public if the measure is endorsed and implemented. The developer reports that results have not been disseminated to those being measured as part of the development process.
- New measure no feedback from those being measured.
- Planned use of measure
- Not publicly reported or used in accountability program, but planned to be used in accountability program. Feedback is essential for programs to improve. Need to develop method for feedback and opportunity to provide feedback.
- Not in current use.
- I would need more information
- This is a new measure. TEP has reviewed.
- Not implemented
- Pass
- True
- Unclear
- No issue
- The developer plans to submit this for use in quality incentive programs.
- Not yet in use

4b. Usability

- No unintended consequences noted.
- Committee discussion of potential unintended consequences would be informative.
- Likely will increase education of patients, incident to in-center HD
- The measure is not yet implemented in a public reporting program, so improvement could not be evaluated. The developer did not provide an assessment of benefits vs. harms.
- Benefits of the performance measure in facilitating progress toward achieving high quality, efficient healthcare for individuals or populations outweigh evidence negative to individuals or populations. No potential harms as the measure is not implemented yet.
- Measure appears sufficiently usable from measure steward's rationale and evidence
- While home based dialysis modalities offer many benefits to ESKD patients, it is labor intensive leading to increased patient/caregiver burden, requires lots of space for storing dialysis materials at home and requires that the patient receives intensive training on how to perform home dialysis. Patients may be encouraged to switch to home modality even if they do not have the appropriate environment or social support to safely perform home dialysis resulting in increased risk of infection/peritonitis, fluid overload/hypertension.

- Educated patients who choose not to embrace home therapy may receive unwanted attention.
- I would need more information.
- Opportunity for unintended consequences exist. Without demonstrated evidence to support the construct, a "change in modality" is being used as a proxy for education and training. There is a risk that patients may be moved to a home modality without actually receiving adequate training or support. This measure may inadvertently/inappropriately encourage facilities to rapidly expand home therapies without adequate resources or training to support these patients and programs
- Potentially could adversely affect efforts to implement Optimal Starts
- High usability
- Appropriate
- I cannot see how this would be a useable metric for reasons stated above
- Due to critical staff shortages, should this be taken into consideration?
- As this is a new measure improvement could not be evaluated. However no unexpected findings or potential harm is anticipated.
- Not clear

Criterion 5: Related and Competing Measures

Related/Competing measures

- The developer did not identify any related or competing measures.

Harmonization

- N/A

Committee Pre-evaluation Comments:

5: Related and Competing Measures

- None noted
- N/A
- No competing measure
- Not applicable
- The developer did not mention any competing measures
- N/A
- N/A
- None
- I would need more information
- None provided
- Not addressed- Potentially could adversely affect efforts to implement Optimal Starts
- None
- True
- None
- None
- There are no competing measure identified.
- None

Member Expression of Support

- Of the one NQF member who has submitted an expression of support, none expressed "support" and one expressed "do not support" for the measure.

Comments

Comment 1 by: David White, American Society of Nephrology; Submitted by David White

TO: National Quality Forum Renal Standing Committee FR: Tod Ibrahim, Executive Vice President, the American Society of Nephrology DA: June 7, 2022 RE: Public Comment: Spring 2022 Renal Measures Dear Members of the National Quality Forum Renal Standing Committee On behalf of the more than 37,000,000 Americans living with kidney diseases and the 21,000 nephrologists, scientists, and other kidney health care professionals who are members of the American Society of Nephrology (ASN), thank you for the opportunity to offer commentary on the five proposed transplantation, vascular access, and modality education measures put forth by the Centers for Medicare and Medicaid Services (CMS)/University of Michigan Kidney Epidemiology and Cost Center (UM-KECC): • Facility-Level Standardized Modality Switch Ratio for Incident Dialysis Patients (SMoSR) • Facility-Level Standardized Fistula Rate for Incident Patients (ISFR) • Practitioner/Group-Level First Year Standard Waitlist Ratio (FYSWR) • Practitioner/Group-Level Percentage of Prevalent Patients Waitlisted (PPPW) • Practitioner/Group-Level Percentage of Prevalent Patients Waitlisted in Active Status (aPPPW) Based on our review, ASN is concerned by several aspects of the measures and offers comment on all five measures submitted to NQF: • Focus on incident maintenance dialysis populations with "stand alone" measures that are independent of measures targeting patients in other stages of kidney diseases such as non-dialysis advanced chronic kidney disease and prevalent dialysis. This siloed focus disadvantages kidney care providers who have provided high quality care for people with advanced CKD, including referral for home dialysis and pre-emptive transplantation and penalizes dialysis providers who assume care of individuals with insufficient care prior to dialysis initiation • Reliance on CMS-2728 data (End Stage Renal Disease Medical Evidence Report Medicare Entitlement and/or Patient Registration) for any risk adjustment including transplant measures • Attribution of measures to dialysis facilities • Lack of adjustment for variables that are critical for patient equity, such as social determinants of health • Focus on dialysis unit-specific measures, without consideration of advanced CKD care and nephrologist-led care Below are comments about the specific measures: Facility-Level Standardized Modality Switch Ratio for Incident Dialysis Patients (SMoSR) The stated goal of the SMoSR measure is to incentivize high quality modality education. However, ASN does not understand how or why the developer arrived at the modality switch rates as a valid proxy for high quality patient engagement and education about modality options. The measure does not indicate the degree or quality of education or the training the patient received in preparation for a modality switch, and the measure may even infringe on the patient-physician relationship. If a dialysis facility or organization is responsible for a metric around dialysis modality switch, that may place the facility inappropriately at odds with conversations and achieved decisions between the patient, the patient's carepartners and the nephrology clinician. While ASN acknowledges that education can be improved for many individuals with advanced chronic kidney disease, we feel strongly that a nephrologist-led care team working with the patient must be at the core of deciding dialysis modality. ASN notes that this measure discounts any prior conversations and education that may have occurred among the nephrology clinician, the patient, and the patient's carepartners. This is extraordinarily non-patient centered and, bizarrely, incentivizes initiation with hemodialysis prior to a modality change. A measure that focuses on modality switches as opposed to receipt of proper patient education and that is attributed to the facility results in a high risk for conflict between informed patient preferences, pre-existing decisions, and dialysis facility incentives. This is bad policy. ASN generally supports CMS's ESRD Treatment Choices (ETC) Model handling of modality switches, wherein the home dialysis rate is aggregated across dialysis facilities under the same legal entity/parent organization within the same Hospital Referral Region, although ASN continues to have

concerns about how transfers among organizations are accounted for. We believe that this HRR approach is fairer, better acknowledges the existing business structure that many larger organizations have developed around home dialysis, and is more easily deciphered by patients, physicians, and providers. Ironically, the proposed measure will actually penalize facilities that have a higher incident home dialysis rate. If a facility serves a population that already has a high home dialysis rate (e.g., 20% Home Dialysis in the service area), then more patients who are likely to desire home dialysis are already performing home dialysis as their initial dialysis modality than facility service areas where fewer (e.g., 10%) maintenance dialysis patients are performing home dialysis. Often times, facilities are involved in preparing patient for home dialysis prior to dialysis initiation. This puts the facility at risk for doing poorly with the metric, despite providing high quality care. Lastly, the "less than thirty days" exclusion in this measure also concerns ASN, since some patients may decide to transition at less than thirty days for valid reasons, although understandably a facility may less often be responsible for home dialysis transitions during the first weeks a patient is receiving in-center dialysis. Additionally, given that individual facilities are relatively small, ASN has concerns regarding the reliability of the proposed metric for most dialysis facilities. We feel strongly that this proposed metric should be completely reconsidered.

Comment 2 by: Lisa McGonigal, Kidney Care Partners; Submitted by Lisa McGonigal, Kidney Care Partners

Facility-Level Standardized Modality Switch Ratio for Incident Dialysis Patients (NQF 3696, CMS) KCP does not support the Standardized Modality Switch Ratio (SMoSR) Measure. CMS indicates the basic premise of the measure is that patients who consent to changing their treatment modality from in-center to home do so as a result of iterative education efforts and effective decision support by the dialysis facility, which can help patients select a modality that is best aligned with their personal goals and values. It was also noted that the Technical Expert Panel (TEP) that convened in Spring 2021 to offer feedback on a draft modality switch measure had broad consensus that: 1) home dialysis rates are very low in the US; 2) a quality measure to monitor facility performance on home dialysis would be useful to patients, providers, and other stakeholders; and 3) there must be greater emphasis on effective and on-going education by both nephrologists and the facility care team to allow more patients to make a more informed modality choice. The TEP also recognized that a majority of switches to home dialysis occur within the first year of beginning chronic dialysis. While KCP agrees with all of the TEP's above conclusions, we remain unsure how the developer arrived at modality switch rates as a valid proxy for proper patient education. If, as stated, the goal is to incentivize improved modality education, this measure misses the mark. Certainly the measure will incentivize switching in-center patients to home dialysis, but there is no mechanism for the measure to discern whether such conversions are the result of the "iterative education efforts and effective decision support" that the developer envisions. Indeed, the measure offers no insight whatsoever into degree or quality of education and training the patient received in preparation for the switch and may even inadvertently infringe on patient choice; any home dialysis-related measure, particularly when tied to financial incentives, must be approached with considerable caution to ensure that patients who should not or do not want to receive home dialysis are not pressured or even coerced into selecting a home modality. We note that KCQA is developing a home dialysis measure set for consideration for National Quality Forum (NQF) endorsement later this year. The paired measure set is developed and designed to promote steady, deliberate performance improvement over time by addressing both sides of the home dialysis utilization equation—uptake and retention. The set pairs a "core" Home Dialysis Rate Measure with a "guardrail" Home Dialysis Retention Measure to counterbalance unopposed incentivization of home prescription and minimize risk of unchecked home dialysis growth. The retention measure will also allow providers to more readily assess the success of their efforts to create a sustainable home program through appropriate patient education, preparation, and support, and to apply targeted quality improvement interventions as needed. We are also concerned that the SMoSR requires use of a complicated and rather confusing two-part regression model connected through an estimated "mixture structure" to account for the many facilities that do not offer home dialysis ("zero-patient facilities"). We believe this issue is more effectively addressed in the KCQA measures, which have adopted the approach deployed in CMS's ESRD Treatment Choices (ETC) Model, wherein the home dialysis rate is aggregated across dialysis facilities under the same legal entity/parent

organization within the same Hospital Referral Region. We believe that this HRR approach is fair and respects the existing business structure many organizations have developed around home dialysis, and is more easily deciphered by both patients and providers. Further, we note that while CMS reports that the TEP supported the basic construct of the SMoSR, KCP staff attended the TEP calls and made note of considerable reservations expressed by TEP members: • The measure addresses only a small subset of patients—incident patients who switched from in-center to home dialysis within the first year of treatment; the TEP voiced concern that the measure would thus ultimately do little to "move the marker" on overall home dialysis utilization within facilities and across dialysis organizations. • Likewise, TEP members argued that as there is significant room for improvement in home dialysis utilization in established patients, the measure should also address prevalent patients. With the exclusion of this population, the measure misses a significant opportunity to drive performance improvement. • Because the measure only gives "credit" for incident patients specifically who switch from in-center to a home modality, there was considerable concern that implementation of the SMoSR in a penalty-based program would create a perverse incentive to, paradoxically, start new patients on in-center dialysis so as to allow for a subsequent modality "switch" to home, for which credit could be received. Finally, as a matter of process, we note that stratification of reliability scores by facility size was not detailed; we are thus unable to discern how widely reliability varies across the spectrum of facility sizes. We are concerned that the reliability for small facilities might be substantially lower than the overall IUR, as has often been the case with other CMS standardized measures. Without evidence to the contrary, KCP is thus concerned the SMoSR reliability may be unacceptably low for small facilities, effectively rendering the metric meaningless for use in performance measurement in this group of providers. KCP believes it is incumbent on CMS to demonstrate reliability for all facilities by providing data by facility size. Similarly, as with CMS's other standardized ratio measures (e.g., the SMR, SHR, SRR, STrR), KCP again strongly recommends that ratio measures be avoided in favor of risk-adjusted rates or year-over-year normalized rates.

Scientific Acceptability Evaluation

RELIABILITY: SPECIFICATIONS

1. **Are submitted specifications precise, unambiguous, and complete so that they can be consistently implemented? ☒ Yes ☒ No**
2. **Briefly summarize any changes to the measure specifications and/or concerns about the measure specifications.**
   - Reviewer 1: The specifications are complex, given the challenges of attributing patients to specific programs or facilities when treatment modalities change. They seem to work, though.
   - Reviewer 2: None.
   - Reviewer 3: The developers should clearly define time zero for the purpose of risk model. Is this a 4-year measure since the developers used 2016-2019 data for testing? I trust that it is a typo when the developers say "if that switch rate is < 1, then the facility is excluded from reporting outcomes." This statement appears multiple times in the application.
   - Reviewer 7: Minor issue: sp.22: the flow chart was not found
   - Reviewer 8: No concerns.
   - Reviewer 9: Ratio of comparison to national average assumes that the national average is standard of care. First durable switch is 30 days or more.
   - Reviewer 11: Narrative indicates that expected value >1 is good and <1 is bad. Assume there is clinical evidence to support these characterizations. As with many of the other dialysis measures, this may be a process measure unless there is evidence that the switch is requested by a physician based on the clinical status of the patient.

RELIABILITY: TESTING

3. **Reliability testing level: ☒ Accountable-Entity Level ☐ Patient/Encounter Level ☐ Neither**
4. **Reliability testing was conducted with the data source and level of analysis indicated for this measure:**

   ☒ Yes ☐ No
5. If accountable-entity level and/or patient/encounter level reliability testing was NOT conducted or if the methods used were NOT appropriate, was **empirical VALIDITY testing** of patient-level data conducted?

   ☐ Yes ☐ No
6. **Assess the method(s) used for reliability testing:**
   - Reviewer 1: The IUR method is acceptable.
   - Reviewer 2: Used bootstrap approach to estimate within facility variation. Appropriate methods.
   - Reviewer 3: For reliability testing, the developers calculated both IUR and PIUR. This method has been used by this group in the past.
   - Reviewer 7: No concerns
   - Reviewer 8: Signal to noise testing was conducted. This test is appropriate for reliability for this type of measure.
   - Reviewer 9: IUR with a bootstrap approach was utilized and adjusted by the use of a PIUR to account for extreme outcomes.
   - Reviewer 11: The developer used any ANOVA approach comparing between and within variance across provider groups. They report an IUR (inter-unit reliability) for the between/total ratio.
   - Reviewer 12: SNR, IUR
7. **Assess the results of reliability testing**
   - Reviewer 1: Results are acceptable, with both IUR and PIUR above .6.
   - Reviewer 2: IUR of 0.605, indicating moderate reliability.
   - Reviewer 3: The IUS is 0.604 for SMoSR and PIUR is 0.606.
   - Reviewer 7: Results indicate moderate STN reliability
   - Reviewer 8: Per the signal to noise test used, the results show an overall mean of 0.605. The finding reflects a modest level of reliability.
   - Reviewer 9: The IUR was 0.605 indicating that 60.9% of the variation was between-facility and 39.1% was within-facility.
   - Reviewer 11: The IUR value was 0.605 for groups with >10 patients and >1 expected events. This represents a moderate level of reliability.
   - Reviewer 12: IUR =0.606
8. Was the method described and appropriate for assessing the proportion of variability due to real differences among measured entities? **NOTE:** If multiple methods used, at least one must be appropriate.

   ☒ Yes ☐ No ☒ Not applicable
9. Was the method described and appropriate for assessing the reliability of ALL critical data elements?

   ☒ Yes ☐ No ☒ Not applicable (patient/encounter level testing was not performed)
10. **OVERALL RATING OF RELIABILITY** (taking into account precision of specifications and all testing results):

    ☐ **High** (NOTE: Can be HIGH only if accountable-entity level testing has been conducted)

    ☒ **Moderate** (NOTE: Moderate is the highest eligible rating if accountable-entity level testing has not been conducted)

    ☒ **Low** (NOTE: Should rate LOW if you believe specifications are NOT precise, unambiguous, and complete or if testing methods/results are not adequate)

☐ **Insufficient** (NOTE: Should rate INSUFFICIENT if you believe you do not have the information you need to make a rating decision)

11. **Briefly explain rationale for the rating of OVERALL RATING OF RELIABILITY and any concerns you may have with the approach to demonstrating reliability.**
    - Reviewer 1: IUR and PIUR values are acceptable.
    - Reviewer 2: Appropriate methods; IUR demonstrated moderate reliability.
    - Reviewer 3: For risk adjusted outcome measures, the IUR is reasonable.
    - Reviewer 7: Results indicate moderate STN reliability
    - Reviewer 8: Response to question #7: Per the signal to noise test used, the results show an overall mean of 0.605. The finding reflects a modest level of reliability.
    - Reviewer 9: Use of IUR as a measure of reliability yielded .0609.
    - Reviewer 11: The methodologies describe to assess reliability were appropriate. The results for the measure score reliability results were moderate. Given that the measure score is the critical value, the overall rating must be biased in that direction.
    - Reviewer 12: This measure is more difficult to understand attribute. Given the A/B attribution with transitions across centers, I am less clear. Rated LOW; Would consider Moderate. [Rationale]

VALIDITY: TESTING

12. **Validity testing level (check all that apply):**

    ☐ **Accountable-Entity Level** ☐ **Patient or Encounter-Level** ☐ **Both**

13. **If patient/encounter level validity testing was provided, was the method described and appropriate for assessing the accuracy of ALL critical data elements? NOTE:** Data element validation from the literature is acceptable.

    ☒ **Yes**

    ☐ **No**

    ☒ **Not applicable** (patient/encounter level testing was not performed)

14. **Method of establishing validity at the accountable-entity level:**

    ☒ **Face validity**

    ☒ **Empirical validity testing at the accountable-entity level**

    ☐ **N/A (accountable-entity level testing not conducted)**

15. **Was the method described and appropriate for assessing conceptually and theoretically sound hypothesized relationships?**

    ☒ **Yes**

    ☐ **No**

    ☐ **Not applicable** (accountable-entity level testing was not performed)

16. **Assess the method(s) for establishing validity**
    - Reviewer 1: The developer conducted several correlational analyses with other proposed or accepted quality measures for dialysis facilities and found the expected set of relationships.
    - Reviewer 2: Assessed the correlation of SMoSR with SMR, FYSMR, SHR, and SWR. Hypothesized no or weak correlations with the first three; a positive correlation with SWR.
    - Reviewer 3: The developers attempted to establish empirical validity of this measure through examining the relationship between this measure and several other measures and provided some conceptual reasonings for the expected outcomes.
    - Reviewer 7: No concerns

- Reviewer 8: The tests of validity seem reasonable in assessing validity for this measure.
- Reviewer 9: Correlation to other metrics was utilized to assess validity, the standardized mortality ratio, the first-year standardized mortality ratio, the standardized hospitalization ratio, the standardized waitlist ratio, ICH-CAHPS, and percentage of home dialysis patients at the facility. The strength of these correlations was assessed with Spearman's Correlation Coefficient.
- Reviewer 11: Tertile comparison of measure scores is rather limited in its ability to demonstrate validity (i.e., stability vs movement among levels). Several of the comparator measures were expected to be miminal or no relationship to the measure score based on the literature.
- Reviewer 12: Validity of the Standardized Modality Switch Ratio was assessed using several different statistical tests to examine the relationship with other facility level quality measures: Standardized Mortality Ratio (SMR), First-Year Standardized Mortality Ratio (FYSMR), Standardized Hospitalization Ratio (SHR), Standardized Waitlist Ratio-Incident Dialysis Patients (SWR), ICH-CAHPS "Providing information to patients", and the percentage of home dialysis patients at the facility. [Summary]

17. **Assess the results(s) for establishing validity**
    - Reviewer 1: The pattern of correlations does support a claim to validity of this measure.
    - Reviewer 2: Results were as expected. Reviewer 3: The results based on SWR are in supportive of the validity of this measure. The results based on SMR, FYSMR, SHR, and ICH-CAHPS are ambiguous and are expected. The results based on the percentage of home dialysis patients at the facility are questionable as the data were used twice.
    - Reviewer 7: Results suggest moderate empirical validity.
    - Reviewer 8: The validity tests across the five tables show mixed results. In general, there is a modest, and acceptable level of validity as seen with these tests.
    - Reviewer 9: Correlation coefficients for many of the hypothesized relationships were very low, either low negative or low positive. The strongest was a positive correlation with the standardized waitlist ratio.
    - Reviewer 11: The two statistically significant relationships with patient experience measures (CAHPS) were in different directions. Confusing. Practitioner group practice performance reported as "Worse than—As— Better than" expected. Median reported values for these groups are 9.5%, 17.55%, and 26.96%, respectively.
    - Reviewer 12: Supporting validity generally. I am curious how others interpret these

VALIDITY: ASSESSMENT OF THREATS TO VALIDITY

18. **Please describe any concerns you have with measure exclusions.**
    - Reviewer 1: None
    - Reviewer 2: None. Performance remains constant with and without exclusions.
    - Reviewer 3: No
    - Reviewer 7: No concerns
    - Reviewer 8: No concerns.
    - Reviewer 9: Missing data was 0.02% for primary cause of ESRD on the CMS-2728 and 0.31% for no BMI on the same form. Analysis was replicated with and without the various exclusions.
    - Reviewer 11: Measure exclusions identified but impact is not addressed meaningfully

19. **Risk Adjustment**

    19a. **Risk-adjustment method**

    ☐ None (only answer Question 20b and 20e) ☒ Statistical model ☐ Stratification

    ☐ Other method assessing risk factors (please specify)

19b. **If not risk-adjusted, is this supported by either a conceptual rationale or empirical analyses?**

☐ Yes ☐ No ☒ Not applicable

19c. **Social risk adjustment:**

19c.1 Are social risk factors included in risk model? ☒ Yes ☒ No ☐ Not applicable

19c.2 Conceptual rationale for social risk factors included? ☒ Yes ☒ No

19c.3 Is there a conceptual relationship between potential social risk factor variables and the measure focus? ☒ Yes ☒ No

19d. **Risk adjustment summary:**

19d.1 All of the risk-adjustment variables present at the start of care? ☒ Yes ☐ No

19d.2 If factors not present at the start of care, do you agree with the rationale provided for inclusion? ☒ Yes ☐ No

19d.3 Is the risk adjustment approach appropriately developed and assessed? ☒ Yes ☐ No

19d.4 Do analyses indicate acceptable results (e.g., acceptable discrimination and calibration) ☒ Yes ☒ No

19d.5. Appropriate risk-adjustment strategy included in the measure? ☒ Yes ☒ No

19e**. Assess the risk-adjustment approach**

- Reviewer 1: This is the one measure in this set where I feel that the developers are incorrect in their decision to leave out a number of social or demographic risk factors in the adjustment model. Factors like race clearly have an impact, and the model's fit would improve with their inclusion. The argument that some entities get better with adjustment and that others get worse is not an argument against risk adjustment - that's exactly what one would expect in any example of risk adjustment. The developer should have included other social/demographic risk factors that would have improved model fit for the risk-adjustment model and would have provided a more accurate measure of quality of care.
- Reviewer 2: Appropriate methods; C-statistic of 0.674, indicating good predictive ability of the risk model. Inclusion of social risk factors had little impact on overall results, so developer choose to exclude.
- Reviewer 3: Independent validation of the risk model is desired.
- Reviewer 8: Regarding testing of the risk model, 2b.27 notes the c-statistic is 0.67. Arguably 0.70 is the minimum test result. Thus, the 0.67 figure is of concern regarding the measure's ability to adjust for risk among the facilities being rated.
- Reviewer 9: Social risk variables were race, ethnicity, Dual eligibility, Area Deprivation Index.
- Reviewer 11: Risk adjustment is described as a two-stage approach involving a Cox model with both stratified and unstratified approach. Ultimately the "denominator of SMoSR for a facility is then the summation of expected probabilities of modality switch from all the patients assigned to that facility."
- Reviewer 12: c-0.67

20. **Please describe any concerns you have regarding the ability to identify meaningful differences in performance.**

For cost/resource use measures, does this measure identify meaningful differences about cost and resource use between the measured entities?

- Reviewer 1: The measure identifies extreme outliers but does not distinguish among entities in the middle of the distribution.
- Reviewer 2: None. 88% of facilities were "as expected"
- Reviewer 3: No concern

- Reviewer 7: No concerns
- Reviewer 8: Using statistical testing to produce ratings of "better", "as expected" and "worse", we see 88% of facilities are rated "as expected". Meaning, 12% are rated as high or low outliers. This is modest degree of variation in performance ratings.
- Reviewer 9: None
- Reviewer 11: Meaningful differences are not presented in a clear and persuasive manner.

21. **Please describe any concerns you have regarding comparability of results if multiple data sources or methods are specified.**
    - Reviewer 1: N/A
    - Reviewer 2: Not applicable.
    - Reviewer 7: Not applicable
    - Reviewer 8: No concerns. As noted in 2b.11, "No, there is only one set of specifications for this measure".
    - Reviewer 9: Not applicable.
22. **Please describe any concerns you have regarding missing data.**
    - Reviewer 1: None
    - Reviewer 2: None
    - Reviewer 3: No concern
    - Reviewer 7: No concerns
    - Reviewer 8: No concerns. The rate of missing data is 0.33%.
    - Reviewer 9: See above.
    - Reviewer 11: Minimal missing data.

For cost/resource use measures ONLY:

If not cost/resource use measure, please skip to question 25.

23. **Are the specifications in alignment with the stated measure intent?**

    ☐ **Yes** ☐ **Somewhat** ☐ **No (If "Somewhat" or "No", please explain)**
24. **Describe any concerns of threats to validity related to attribution, the costing approach, carve outs, or truncation (approach to outliers):**
25. **OVERALL RATING OF VALIDITY taking into account the results and scope of all testing and analysis of potential threats.**

    ☒ **High** (NOTE: Can be HIGH only if accountable-entity level testing has been conducted)

    ☒ **Moderate** (NOTE: Moderate is the highest eligible rating if accountable-entity level testing has NOT been conducted)

    ☒ **Low** (NOTE: Should rate LOW if you believe that there are threats to validity and/or relevant threats to validity were not assessed OR if testing methods/results are not adequate)

    ☐ **Insufficient** (NOTE: For instrument-based measures and some composite measures, testing at both the accountable-entity level and the patient/encounter level is required; if not conducted, should rate as INSUFFICIENT.)
26. **Briefly explain rationale for rating of OVERALL RATING OF VALIDITY and any concerns you may have with the developers' approach to demonstrating validity.**

- Reviewer 1: I think the measure has moderate validity in spite of my concerns about risk adjustment - it would be better with better risk adjustment.
- Reviewer 2: Appropriate methods; robust results with hypothesized relationships.
- Reviewer 7: See comments above
- Reviewer 8: My response to question 17: The validity tests across the five tables show mixed results. In general, there is a modest, and acceptable level of validity as seen with these tests. My response to question 19: Regarding testing of the risk model, 2b.27 notes the c-statistic is 0.67. Arguably 0.70 is the minimum test result. Thus, the 0.67 figure is of concern regarding the measure's ability to adjust for risk among the facilities being rated.
- Reviewer 9: Correlation with other measures of quality was weak and this was utilized as the major rationale for validity.
- Reviewer 11: Given the minimal differences among facilities, modest at best risk adjustment to the measure, and the lack of valid discrimination among facilities, this measure has low validity.
- Reviewer 12: I am interested to hear others' take on this. MOD could be LOW.

FOR COMPOSITE MEASURES ONLY: Empirical analyses to support composite construction

27. **What is the level of certainty or confidence that the empirical analysis demonstrates that the component measures add value to the composite and that the aggregation and weighting rules are consistent with the quality construct?**

    ☐ **High**

    ☐ **Moderate**

    ☐ **Low**

    ☐ **Insufficient**

28. **Briefly explain rationale for rating of EMPIRICAL ANALYSES TO SUPPORT COMPOSITE CONSTRUCTION**
    - N/A

ADDITIONAL RECOMMENDATIONS

29. **If you have listed any concerns in this form, do you believe these concerns warrant further discussion by the multi-stakeholder Standing Committee? If so, please list those concerns below.**
    - N/A

Criteria 1: Importance to Measure and Report

1a. Evidence

Extent to which the specific measure focus is evidence-based, important to making significant gains in healthcare quality, and improving health outcomes for a specific high-priority (high-impact) aspect of healthcare where there is variation in or overall less-than-optimal performance. Measures must be judged to meet all sub criteria to pass this criterion and be evaluated against the remaining criteria

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Please separate added or updated information from the most recent measure evaluation within each question response in the Importance to Measure and Report: Evidence section. For example:

2021 Submission:

Updated evidence information here.

2018 Submission:

Evidence from the previous submission here.

1a.01. Provide a logic model.

Briefly describe the steps between the healthcare structures and processes (e.g., interventions, or services) and the patient's health outcome(s). The relationships in the diagram should be easily understood by general, non-technical audiences. Indicate the structure, process or outcome being measured.

[Response Begins]

Dialysis modality is a health status as it impacts other clinical outcomes (e.g., anemia, cardiovascular related outcomes, infection) and patient reported outcomes (e.g., experience of care). The SMoSR measure reports on the modality outcome of in-center hemodialysis patients who in their first year of treatment switch to a home dialysis modality. Switches to home dialysis in the first year reflect robust education, effective presentation of modality educational materials (facility process), and facilitation of patient decision making by the dialysis unit (facility process). Both are processes owned by the dialysis facility and codified in CMS Regulations (Conditions for Coverage). Additionally, the Advancing American Kidney Health Initiative and the current ESRD Treatment Choices and Kidney Care Choices models place uptake of home dialysis modality (along with transplantation) as one of the metrics on which facilities will be evaluated.

The basic premise of the Standardized Modality Switch Ratio measure is that patients consented to changing their treatment modality to a home modality after initially starting on in-center hemodialysis, as a result of on-going education efforts and effective decision support by the dialysis facility. These processes can lead to helping patients select a home dialysis modality that may best fit with their personal goals and values:

Facility identifies incident patients who are on in-center hemodialysis modality → Facility provides effective education to facilitate patient decision making for a home modality →Improves alignment between patients' goals of care and values and their dialysis modality →Increase rate in switches from in-center to home dialysis modality.

[Response Ends]

1a.02. Provide evidence that the target population values the measured outcome, process, or structure and finds it meaningful.

Describe how and from whom input was obtained.

[Response Begins]

A Technical Expert Panel was convened in spring 2021 to obtain feedback on a draft measure of modality switches from in-center to home dialysis (UM-KECC, 2021). The TEP was co-chaired by a clinical nephrologist and a patient. The TEP was made up of 6 ESRD patients that had experience with in-center and/or home dialysis, and 8 clinicians (nephrologists and nephrology nurses) that treat ESRD dialysis patients. Over the course of the discussion there was strong consensus that 1) rates of home dialysis are very low in the U.S., and 2) that there needs to be greater emphasis on on-going and effective education by nephrologists and the facility care team to allow more patients to make an informed choice for home dialysis. It was also recognized that well over a majority of switches to home dialysis occur within the first year of beginning chronic dialysis.

- Physicians play a critical role in providing dialysis education. If physicians are knowledgeable about home dialysis, then they are more likely to provide balanced education to the patient while considering co-morbidities that may impact a modality selection. Some patient TEP members described bias (toward in-center HD) in the education they experienced, where the risks of home dialysis were highlighted and over-emphasized and those of in-center dialysis downplayed.
- Modality education and decision making ideally should occur in the pre-dialysis stages. However, since many patients start dialysis abruptly, and may have had little or no pre-dialysis education, this process should continue in the dialysis facility after initiating chronic dialysis. Modality education should be an iterative process since patients new to dialysis may not be ready to absorb information or make a modality decision immediately after starting in-center HD.

Overall there was broad consensus that home dialysis is underutilized and that a quality measure to monitor facility performance would be useful to patients, providers, and other stakeholders. The TEP supported the basic construct of the Standardized Modality Switch Ratio (SMoSR) Measure.

University of Michigan Kidney Epidemiology and Cost Center. Effective Availability and Utilization of Home Dialysis Technical Expert Panel Summary Report, Prepared for The Centers for Medicare and Medicaid Services. June, 2021.

[Response Ends]

1a.03. Provide empirical data demonstrating the relationship between the outcome (or PRO) and at least one healthcare structure, process, intervention, or service.

[Response Begins]

Home dialysis rates remain low in the United States compared with many other countries, hovering around 12% (Briggs 2019). Because there are not formal randomized controlled trials of modality uptake, the evidence for SMoSR is based on a large body of observational studies in the U.S. as well as outside the U.S. such as Canada, several European countries, and Australia and New Zealand.

We evaluated studies that examined the epidemiology and characteristics of home dialysis uptake; educational interventions and processes to support shared-decision making; and studies comparing or assessing outcomes (mortality; hospitalization) between a home dialysis modality (i.e., peritoneal dialysis) and in-center hemodialysis, or the association of home modalities with comorbidities and other health outcomes.

Clinical, operational, economic and patient factors have been identified as barriers to uptake of home dialysis modalities (Chan 2019). Clinical factors include lack of physician competency in prescribing home dialysis modalities; operational include lack of clinician and staff training; economic obstacles include lack of sufficient housing or storage space for dialysis supplies; and patient barriers include lack of adequate education. Studies also have identified demographic characteristics of black race, male sex, older age, and comorbidities as predictors of low uptake of home dialysis; while small dialysis facility size and low physician and nurse experience with home dialysis are facility level barriers.

Studies that examine the role and impact of education on home modality uptake show that about 30% of chronic dialysis patients have reported their modality selection was not really their choice or did not feel as though they made an informed choice, and that this percentage is higher among in-center hemodialysis (ICHD) patients (Dahlerus 2016; Van Biesen 2014; Song 2013; Winterbottom 2012). Studies have also found that there is a mismatch between stated preference for dialysis modality (i.e., home dialysis) and the actual modality on which patients start. The preferred modality was a home therapy but in many cases patients started on in-center hemodialysis (Pyart 2018; Keating 2014; Liebman 2012). This suggests existing educational efforts fall short of supporting decision making by the patient. Specifically, decision-making efficacy and satisfaction of modality selection has been reported as greater among PD vs in-center HD patients (Zee 2018)

Because of the lack of RCTs comparing dialysis modalities and outcomes, the current evidence is observational in nature. Some studies have shown a survival advantage associated with PD as an initial modality however evidence is mixed about the longer term outcomes and survival benefit for PD versus in-center hemodialysis. As such, in-center and home dialysis are generally considered equivalent with respect to hospitalization rates and mortality. In one meta-review, some differences were observed in physical and mental quality of life domains between patients on PD versus in-center hemodialysis (Budhram 2020)

The evidence indicates that persistently low rates of home dialysis use are associated with both patient and facility level factors. Education and shared decision making interventions suggest an opportunity to improve uptake of home dialysis. Moreover, home modalities offer patients potential flexibility and independence.

Collectively these studies support the construct of the SMoSR which is an indicator of successful education by the facility to facilitate a decision to switch to a home modality, through on-going educational efforts after a patient starts on in-center hemodialysis.

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Chan CT, Blankestijn PJ, Dember LM, Gallieni M, Harris DCH, Lok CE, Mehrotra R, Stevens PE, Wang AY, Cheung M, Wheeler DC, Winkelmayer WC, Pollock CA; Conference Participants. Dialysis initiation, modality choice, access, and prescription: conclusions from a Kidney Disease: Improving Global Outcomes (KDIGO) Controversies Conference Kidney Int. 2019 Jul;96(1):37-47. doi: 10.1016/j.kint.2019.01.017. Epub 2019 Apr 13.

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Zee J, Zhao J, Subramanian L, Perry E, Bryant N, McCall M, Restovic Y, Torres D, Robinson BM, Pisoni RL, Tentori F. Perceptions about the dialysis modality decision process among peritoneal dialysis and in-center hemodialysis patients BMC Nephrol. 2018 Oct 29;19(1):298. doi: 10.1186/s12882-018-1096-x.

[Response Ends]

1b. Gap in Care/Opportunity for Improvement and Disparities

1b.01. Briefly explain the rationale for this measure.

Explain how the measure will improve the quality of care, and list the benefits or improvements in quality envisioned by use of this measure.

[Response Begins]

Home dialysis rates remain low in the United States compared with many other countries (as of 2019, 10.8% PD, 1.8% HHD). This measure will allow one to compare the effectiveness of facility modality education and/or effective utilization of home dialysis modalities. This will be a facility outcome metric for comparison across the US including longitudinal monitoring. It is patient centered in that it is intended to facilitate on-going education that may result in patients choosing a home modality, particularly if there was no pre-dialysis modality education provided. The quality of care will be improved by better alignment between patients' goals and values and their dialysis modality. The focus is on incident patients since most modality changes occur during the first year and likely reflect robust education, effective presentation, and facilitation by the dialysis unit.

[Response Ends]

1b.02. Provide performance scores on the measure as specified (current and over time) at the specified level of analysis.

Include mean, std dev, min, max, interquartile range, and scores by decile. Describe the data source including number of measured entities; number of patients; dates of data; if a sample, characteristics of the entities include. This information also will be used to address the sub-criterion on improvement (4b) under Usability and Use.

[Response Begins]

After applying all exclusion criteria, we evaluated all Medicare-certified dialysis facilities (n=6,039) treating incident patients (n=316,382) that had at least 1 expected patient modality switch in the reporting years. The distribution of the Standardized Modality Switch Ratio (SMoSR) across these facilities is shown in the table below. The mean value was 1.07 and the standard deviation was 1.00.

Q1	Median	Q3	Mean	Std Dev
0.37	0.84	1.52	1.07	1.00

Distribution of SMoSR across facilities

Deciles of Standardized Modality Switch Ratio

*Note, there are 6039 facilities included in this analysis. On average, each group had 604 facilities. However, 933 facilities had an SMoSR of 0. All those facilities were grouped into Decile 1 and remaining 274 facilities were grouped into Decile 2.

Decile 1: N=933, Mean=0, Std Dev = 0

Decile 2: N=274, Mean=0.21, Std Dev = 0.04

Decile 3: N=604, Mean=0.37, Std Dev = 0.05

Decile 4: N=604, Mean=0.55, Std Dev = 0.05

Decile 5: N=604, Mean=0.74, Std Dev = 0.06

Decile 6: N=604, Mean=0.95, Std Dev = 0.07

Decile 7: N=604, Mean=1.21, Std Dev = 0.08

Decile 8: N=604, Mean=1.53, Std Dev = 0.10

Decile 9: N=604, Mean=1.97, Std Dev = 0.17

Decile 10: N=604, Mean=3.26, Std Dev = 1.12

[Response Ends]

1b.03. If no or limited performance data on the measure as specified is reported above, then provide a summary of data from the literature that indicates opportunity for improvement or overall less than optimal performance on the specific focus of measurement. Include citations.

[Response Begins]

N/A

[Response Ends]

1b.04. Provide disparities data from the measure as specified (current and over time) by population group, e.g., by race/ethnicity, gender, age, insurance status, socioeconomic status, and/or disability.

Describe the data source including number of measured entities; number of patients; dates of data; if a sample, characteristics of the entities included. Include mean, std dev, min, max, interquartile range, and scores by decile. For measures that show high levels of performance, i.e., "topped out", disparities data may demonstrate an opportunity for improvement/gap in care for certain sub-populations. This information also will be used to address the sub-criterion on improvement (4b) under Usability and Use.

[Response Begins]

Race and ethnicity have been shown to be predictors of switches to a home modality. Using data from 2016-2019 (described above in 1b.02), we observed that black, Native American and Asian/Pacific Islander patients had lower hazard of a modality switch (0.59, 0.67 and 0.86, respectively) compared to white patients. Hispanic patients had lower hazard of a modality switch (HR = 0.67) compared to non-Hispanic patients. The hazards of modality switches were not statistically significant between male and female patients (HR=0.99, 95% CI: 0.96, 1.02). Further, patients employed 6 months prior to the onset of ESRD had a higher hazard of modality switch (HR=2.00) than patients that were unemployed. Medicare dual eligible patients had a lower hazard of a modality switch (HR=0.57) than other patients.

Refer to Risk Adjustment section (2b.24)) for further analyses on race, ethnicity, sex and socioeconomic status.

[Response Ends]

1b.05. If no or limited data on disparities from the measure as specified is reported above, then provide a summary of data from the literature that addresses disparities in care on the specific focus of measurement. Include citations. Not necessary if performance data provided in above.

[Response Begins]

N/A

[Response Ends]

Criteria 2: Scientific Acceptability of Measure Properties

Extent to which the measure, as specified, produces consistent (reliable) and credible (valid) results about the quality of care when implemented. Measures must be judged to meet the sub criteria for both reliability and validity to pass this criterion and be evaluated against the remaining criteria.

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sp.01. Provide the measure title.

Measure titles should be concise yet convey who and what is being measured (see What Good Looks Like).

[Response Begins]

Standardized Modality Switch Ratio for Incident Dialysis Patients (SMoSR)

[Response Ends]

sp.02. Provide a brief description of the measure.

Including type of score, measure focus, target population, timeframe, (e.g., Percentage of adult patients aged 18-75 years receiving one or more HbA1c tests per year).

[Response Begins]

The standardized modality switch ratio (SMoSR) is defined to be the ratio of the number of observed modality switches (from in-center to home dialysis—peritoneal or home hemodialysis) that occur for adult incident ESRD dialysis patients treated at a particular facility, to the number of modality switches (from in-center to

home dialysis—peritoneal or home hemodialysis) that would be expected given the characteristics of the dialysis facility's patients and the national norm for dialysis facilities. The measure includes only the first durable switch that is defined as lasting 30 continuous days or longer.

The SMoSR estimates the relative switch rate (from in-center to home dialysis) for a facility, as compared to the national switch rate. Qualitatively, the degree to which the facility's SMoSR varies from 1.00 is the degree to which it exceeds (> 1.00) or is below (< 1.00) the national modality switch rates for patients with the same characteristics as those in the facility. Ratios greater than 1.00 indicate better than expected performance while ratios <1.00 indicate worse than expected performance.

When used for public reporting, the measure calculation will be restricted to facilities with at least one expected modality switch in the reporting year. This restriction is required to ensure patients cannot be identified due to small cell size.

[Response Ends]

sp.04. Check all the clinical condition/topic areas that apply to your measure, below.

Please refrain from selecting the following answer option(s). We are in the process of phasing out these answer options and request that you instead select one of the other answer options as they apply to your measure.

Please do not select:

- *Surgery: General*

[Response Begins]

Renal

Renal: End Stage Renal Disease (ESRD)

[Response Ends]

sp.05. Check all the non-condition specific measure domain areas that apply to your measure, below.

[Response Begins]

Access to Care

Person-and Family-Centered Care: Person-and Family-Centered Care

[Response Ends]

sp.06. Select one or more target population categories.

Select only those target populations which can be stratified in the reporting of the measure's result.

Please refrain from selecting the following answer option(s). We are in the process of phasing out these answer options and request that you instead select one of the other answer options as they apply to your measure.

Please do not select:

- *Populations at Risk: Populations at Risk*

[Response Begins]

Adults (Age >= 18)

Elderly (Age >= 65)

Populations at Risk: Individuals with multiple chronic conditions

[Response Ends]

sp.07. Select the levels of analysis that apply to your measure.

Check ONLY the levels of analysis for which the measure is SPECIFIED and TESTED.

Please refrain from selecting the following answer option(s). We are in the process of phasing out these answer options and request that you instead select one of the other answer options as they apply to your measure.

Please do not select:

- *Clinician: Clinician*
- *Population: Population*

[Response Begins]

Facility

[Response Ends]

sp.08. Indicate the care settings that apply to your measure.

Check ONLY the settings for which the measure is SPECIFIED and TESTED.

[Response Begins]

Outpatient Services

[Response Ends]

sp.09. Provide a URL link to a web page specific for this measure that contains current detailed specifications including code lists, risk model details, and supplemental materials.

Do not enter a URL linking to a home page or to general information. If no URL is available, indicate "none available".

[Response Begins]

N/A

[Response Ends]

sp.11. Attach the data dictionary, code table, or value sets (and risk model codes and coefficients when applicable). Excel formats (.xlsx or .csv) are preferred.

Attach an excel or csv file; if this poses an issue, contact staff. Provide descriptors for any codes. Use one file with multiple worksheets, if needed.

[Response Begins]

Available in attached Excel or csv file

[Response Ends]

Attachment: 3696_SMoSR Data_Dictionary.xlsx

For the question below: state the outcome being measured. Calculation of the risk-adjusted outcome should be described in sp.22.

sp.12. State the numerator.

Brief, narrative description of the measure focus or what is being measured about the target population, i.e., cases from the target population with the target process, condition, event, or outcome).

DO NOT include the rationale for the measure.

[Response Begins]

Observed number of switches from in-center hemodialysis to a home dialysis modality (peritoneal dialysis or home hemodialysis) among eligible patients at the facility during the time period.

[Response Ends]

For the question below: describe how the observed outcome is identified/counted. Calculation of the risk-adjusted outcome should be described in sp.22.

sp.13. Provide details needed to calculate the numerator.

All information required to identify and calculate the cases from the target population with the target process, condition, event, or outcome such as definitions, time period for data collection, specific data collection items/responses, code/value sets.

Note: lists of individual codes with descriptors that exceed 1 page should be provided in an Excel or csv file in required format at sp.11.

[Response Begins]

Information on modality type and modality switches is obtained from several sources which include CROWNWeb, Medicare dialysis claims, and the Medical Evidence Form (Form CMS-2728).

The numerator includes only the first durable switch to a home dialysis modality lasting >= 30 continuous days. An eligible modality switch is considered as an in-center hemodialysis patient that switches to home dialysis (peritoneal dialysis or home hemodialysis) within 365 days of ESRD onset, and the home modality is maintained for >= 30 days. Only the first durable modality switch is included if patients have multiple switches. Modality switches during the first 30 days of dialysis at a facility are not counted for that facility.

[Response Ends]

For the question below: state the target population for the outcome. Calculation of the risk-adjusted outcome should be described in sp.22.

sp.14. State the denominator.

Brief, narrative description of the target population being measured.

[Response Begins]

Expected number of switches from in-center hemodialysis to a home dialysis modality (peritoneal dialysis or home hemodialysis) among eligible patients at the facility during the time period, given the national average of modality switches, and patient case-mix at the facility.

[Response Ends]

For the question below: describe how the target population is identified. Calculation of the risk-adjusted outcome should be described in sp.22.

sp.15. Provide details needed to calculate the denominator.

All information required to identify and calculate the target population/denominator such as definitions, time period for data collection, specific data collection items/responses, code/value sets.

Note: lists of individual codes with descriptors that exceed 1 page should be provided in an Excel or csv file in required format at sp.11.

[Response Begins]

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's day to a facility (or no facility, in some cases) based on a set of conventions below.

General Inclusion Criteria for Chronic Dialysis Patients:

This measure includes all eligible incident ESRD dialysis patients and is not restricted to Medicare beneficiaries. To be included in the denominator, the patient must be ESRD as defined by a submitted Medical Evidence Form (Form CMS-2728). Patients must be at least 18 years old as of the first day of ESRD. In order to exclude patients who only received temporary dialysis therapy, we assign patients to a facility only after they have been on dialysis there for the past 30 days.

Identifying Facility Treatment Histories for Each Patient and Patient Attribution:

For each patient, we identify the dialysis provider each month using a combination of data from CROWNWeb, Medicare-paid dialysis claims (primarily outpatient), and the Medical Evidence Form (Form CMS-2728). These sources are used to identify patients that are on chronic in-center or home dialysis (peritoneal or home hemodialysis) for the entire reporting period. Starting with the 1st day of ESRD, we attribute patients to facilities according to the following rules. If the initial modality is home dialysis, we exclude the home modality period from the denominator and consider the 1st day (following) in-center dialysis as the 1st day at risk. A patient is attributed to a facility once the patient has been treated there for the past 30 days. When a patient transfers from one facility to another, the patient continues to be attributed to the original facility for 30 days and then is attributed to the destination facility from day 31. In particular, a patient is attributed to their current facility on 31st day of ESRD if that facility had treated him or her for the past 30 days. For example, if a patient who is on in-center hemodialysis changes from facility A to B and then switches to home dialysis within 30 days of arriving at facility B, facility A would get credit for the switch. In this scenario, given the short time-frame between changing facilities and switching modalities, it is likely that facility A is responsible for the modality education. After 30 days, the switch would be attributed to the receiving facility (i.e., facility B). When a patient is not treated in a single facility for a span of 30 days (for instance, if there were two facility transfers within 30 days of each other), we do not attribute that patient to any facility.

We use the number of days at risk in each of these patient-records to calculate the expected number of modality switches for that patient-record, and sum the total number of expected modality switches during all patient-records at the facility as the expected number of modality switches for that facility.

[Response Ends]

sp.16. Describe the denominator exclusions.

Brief narrative description of exclusions from the target population.

[Response Begins]

The following exclusions are applied to the denominator:

- Patient's time at risk under hospice care
- Patient's time at risk when in a nursing home and on home hemodialysis
- Pediatric patients (less than 18 years of age)
- Patients with no CMS-2728 Medical Evidence Form (i.e., AKI patients on dialysis but not designated as ESRD)

Patients who are attributed to clinics with fewer than 1 expected modality switch are not excluded from the measure. All *patients* who meet the denominator inclusion criteria are included and used to model a given facilities expected switch rate to home dialysis. If that switch rate is <1, then the *facility* is excluded from reporting outcomes.

[Response Ends]

sp.17. Provide details needed to calculate the denominator exclusions.

All information required to identify and calculate exclusions from the denominator such as definitions, time period for data collection, specific data collection items/responses, code/value sets – Note: lists of individual codes with descriptors that exceed 1 page should be provided in an Excel or csv file in required format at sp.11.

[Response Begins]

Determination of eligible patients is based on a non-missing Medical Evidence Form (Form CMS-2728). The intent of excluding patients with no Form 2728 is to exclude patients with Acute Kidney Injury that are receiving temporary outpatient dialysis.

The nursing home status information is determined from the Nursing Home Minimum Dataset (MDS). Time at risk for patients in a nursing home on home hemodialysis is excluded from the measure.

The patient's age is determined by subtracting the patient's date of birth from the first day of the reporting month. Patients that are <18 years old as of the first day of the reporting month are excluded.

Hospice status is determined from a separate CMS file that contains final action claims submitted by Hospice providers. Once a beneficiary elects a Hospice, all Hospice related claims will be found in this file, regardless if the beneficiary is in Medicare fee-for-service or in a Medicare managed care plan. Patients' time at risk is censored from the date of the first hospice care claim.

[Response Ends]

sp.18. Provide all information required to stratify the measure results, if necessary.

Include the stratification variables, definitions, specific data collection items/responses, code/value sets, and the risk-model covariates and coefficients for the clinically-adjusted version of the measure when appropriate. Note: lists of individual codes with descriptors that exceed 1 page should be provided in an Excel or csv file in required format in the Data Dictionary field.

[Response Begins]

N/A

[Response Ends]

sp.19. Select the risk adjustment type.

Select type. Provide specifications for risk stratification and/or risk models in the Scientific Acceptability section.

[Response Begins]

Statistical risk model

[Response Ends]

sp.20. Select the most relevant type of score.

Attachment: If available, please provide a sample report.

[Response Begins]

Ratio

[Response Ends]

sp.21. Select the appropriate interpretation of the measure score.

Classifies interpretation of score according to whether better quality or resource use is associated with a higher score, a lower score, a score falling within a defined interval, or a passing score

[Response Begins]

Better quality = Higher score

[Response Ends]

sp.22. Diagram or describe the calculation of the measure score as an ordered sequence of steps.

Identify the target population; exclusions; cases meeting the target process, condition, event, or outcome; time period of data, aggregating data; risk adjustment; etc.

[Response Begins]

see attached flowchart

[Response Ends]

sp.25. If measure is based on a sample, provide instructions for obtaining the sample and guidance on minimum sample size.

[Response Begins]

N/A

[Response Ends]

sp.28. Select only the data sources for which the measure is specified.

[Response Begins]

Claims

Registry Data

[Response Ends]

sp.29. Identify the specific data source or data collection instrument.

For example, provide the name of the database, clinical registry, collection instrument, etc., and describe how data are collected.

[Response Begins]

Data are derived from an extensive national ESRD patient database, which is primarily based on the Renal Management Information System (REMIS), CROWNWeb facility-reported clinical and administrative data (including CMS-2728 Medical Evidence Form, CMS-2746 Death Notification Form, and CMS-2744 Annual Facility Survey Form and patient tracking data), the Medicare Enrollment Database (EDB), and Medicare dialysis claims data (primarily outpatient). In addition, the database includes transplant data from the Scientific Registry of Transplant Recipients (SRTR), and data from the Nursing Home Minimum Dataset, the Quality Improvement Evaluation System (QIES) Business Intelligence Center (QBIC) (which includes Provider and Survey and Certification data from Automated Survey Processing Environment (ASPEN)), and the Dialysis Facility Compare (DFC). Hospice information is obtained from Medicare Part A Hospice claims submitted by Hospice providers.

Tracking by dialysis provider and treatment modality is available for all patients including those with only partial or no Medicare coverage

[Response Ends]

sp.30. Provide the data collection instrument.

[Response Begins]

No data collection instrument provided

[Response Ends]

2a. Reliability

Measure testing must demonstrate adequate reliability and validity in order to be recommended for endorsement. Testing may be conducted for data elements and/or the computed measure score. Testing information and results should be entered in the appropriate fields in the Scientific Acceptability sections of the Measure Submission Form.

• Measures must be tested for all the data sources and levels of analyses that are specified. If there is more than one set of data specifications or more than one level of analysis, contact NQF staff about how to present all the testing information in one form.

• All required sections must be completed.

• For composites with outcome and resource use measures, Questions 2b.23-2b.37 (Risk Adjustment) also must be completed.

• If specified for multiple data sources/sets of specifications (e.g., claims and EHRs), Questions 2b.11-2b.13 also must be completed.

• An appendix for supplemental materials may be submitted (see Question 1 in the Additional section), but there is no guarantee it will be reviewed.

• Contact NQF staff with any questions. Check for resources at the Submitting Standards webpage.

• For information on the most updated guidance on how to address social risk factors variables and testing in this form refer to the release notes for the 2021 Measure Evaluation Criteria and Guidance.

Note: The information provided in this form is intended to aid the Standing Committee and other stakeholders in understanding to what degree the testing results for this measure meet NQF's evaluation criteria for testing.

2a. Reliability testing demonstrates the measure data elements are repeatable, producing the same results a high proportion of the time when assessed in the same population in the same time period and/or that the measure score is precise. For instrument-based measures (including PRO-PMs) and composite performance measures, reliability should be demonstrated for the computed performance score.

2b1. Validity testing demonstrates that the measure data elements are correct and/or the measure score correctly reflects the quality of care provided, adequately identifying differences in quality. For instrument based measures (including PRO-PMs) and composite performance measures, validity should be demonstrated for the computed performance score.

2b2. Exclusions are supported by the clinical evidence and are of sufficient frequency to warrant inclusion in the specifications of the measure;

AND

If patient preference (e.g., informed decision-making) is a basis for exclusion, there must be evidence that the exclusion impacts performance on the measure; in such cases, the measure must be specified so that the information about patient preference and the effect on the measure is transparent (e.g., numerator category computed separately, denominator exclusion category computed separately).

2b3. For outcome measures and other measures when indicated (e.g., resource use):

• an evidence-based risk-adjustment strategy (e.g., risk models, risk stratification) is specified; is based on patient factors (including clinical and social risk factors) that influence the measured outcome and are present at start of care; 14,15 and has demonstrated adequate discrimination and calibration

OR

• rationale/data support no risk adjustment/ stratification.

2b4. Data analysis of computed measure scores demonstrates that methods for scoring and analysis of the specified measure allow for identification of statistically significant and practically/clinically meaningful 16 differences in performance;

OR

there is evidence of overall less-than-optimal performance.

2b5. If multiple data sources/methods are specified, there is demonstration they produce comparable results.

2b6. Analyses identify the extent and distribution of missing data (or nonresponse) and demonstrate that performance results are not biased due to systematic missing data (or differences between responders and non-responders) and how the specified handling of missing data minimizes bias.

2c. For composite performance measures, empirical analyses support the composite construction approach and demonstrate that:

2c1. the component measures fit the quality construct and add value to the overall composite while achieving the related objective of parsimony to the extent possible; and

2c2. the aggregation and weighting rules are consistent with the quality construct and rationale while achieving the related objective of simplicity to the extent possible.

(if not conducted or results not adequate, justification must be submitted and accepted)

Definitions

Reliability testing applies to both the data elements and computed measure score. Examples of reliability testing for data elements include, but are not limited to: inter-rater/abstractor or intra-rater/abstractor studies; internal consistency for multi-item scales; test-retest for survey items. Reliability testing of the measure score addresses precision of measurement (e.g., signal-to-noise).

Validity testing applies to both the data elements and computed measure score. Validity testing of data elements typically analyzes agreement with another authoritative source of the same information. Examples of validity testing of the measure score include, but are not limited to: testing hypotheses that the measures scores indicate quality of care, e.g., measure scores are different for groups known to have differences in quality assessed by another valid quality measure or method; correlation of measure scores with another valid indicator of quality for the specific topic; or relationship to conceptually related measures (e.g., scores on process measures to scores on outcome measures). Face validity of the measure score as a quality indicator may be adequate if accomplished through a systematic and transparent process, by identified experts, and explicitly addresses whether performance scores resulting from the measure as specified can be used to distinguish good from poor quality. The degree of consensus and any areas of disagreement must be provided/discussed.

Examples of evidence that an exclusion distorts measure results include, but are not limited to: frequency of occurrence, variability of exclusions across providers, and sensitivity analyses with and without the exclusion.

Patient preference is not a clinical exception to eligibility and can be influenced by provider interventions.

Risk factors that influence outcomes should not be specified as exclusions.

With large enough sample sizes, small differences that are statistically significant may or may not be practically or clinically meaningful. The substantive question may be, for example, whether a statistically significant difference of one percentage point in the percentage of patients who received smoking cessation counseling (e.g., 74 percent v. 75 percent) is clinically meaningful; or whether a statistically significant difference of $25 in cost for an episode of care (e.g., $5,000 v.$5,025) is practically meaningful. Measures with overall less-than-optimal performance may not demonstrate much variability across providers.

Please separate added or updated information from the most recent measure evaluation within each question response in the Importance to Scientific Acceptability sections. For example:

2021 Submission:

Updated testing information here.

2018 Submission:

Testing from the previous submission here.

2a.01. Select only the data sources for which the measure is tested.

[Response Begins]

Claims

Registry Data

[Response Ends]

2a.02. If an existing dataset was used, identify the specific dataset.

The dataset used for testing must be consistent with the measure specifications for target population and healthcare entities being measured; e.g., Medicare Part A claims, Medicaid claims, other commercial insurance, nursing home MDS, home health OASIS, clinical registry).

[Response Begins]

National CROWNWeb data from January 2016-December 2019 and Medicare outpatient dialysis claims data from January 2016 – December 2019.

Data are derived from an extensive national ESRD patient database, which is primarily based on the Renal Management Information System (REMIS), CROWNWeb facility-reported clinical and administrative data (including CMS-2728 Medical Evidence Form, CMS-2746 Death Notification Form, and CMS-2744 Annual Facility Survey Form and patient tracking data), the Medicare Enrollment Database (EDB), and Medicare dialysis claims data (primarily outpatient). In addition, the database includes transplant data from the Scientific Registry of Transplant Recipients (SRTR), and data from the Nursing Home Minimum Dataset, the Quality Improvement Evaluation System (QIES) Business Intelligence Center (QBIC) (which includes Provider and Survey and Certification data from Automated Survey Processing Environment (ASPEN)), and the Dialysis Facility Compare (DFC). Hospice information is obtained from Medicare Part A hospice care claims submitted by Hospice providers.

[Response Ends]

2a.03. Provide the dates of the data used in testing.

Use the following format: "MM-DD-YYYY - MM-DD-YYYY"

[Response Begins]

01-01-2016 to 12-31-2019

[Response Ends]

2a.04. Select the levels of analysis for which the measure is tested.

Testing must be provided for all the levels specified and intended for measure implementation, e.g., individual clinician, hospital, health plan.

Please refrain from selecting the following answer option(s). We are in the process of phasing out these answer options and request that you instead select one of the other answer options as they apply to your measure.

Please do not select:

- *Clinician: Clinician*

- *Population: Population*

[Response Begins]

Facility

[Response Ends]

2a.05. List the measured entities included in the testing and analysis (by level of analysis and data source).

Identify the number and descriptive characteristics of measured entities included in the analysis (e.g., size, location, type); if a sample was used, describe how entities were selected for inclusion in the sample.

[Response Begins]

Patients on both home (less than 30 days) and in-center hemodialysis during January 2016-December 2019 and starting chronic dialysis within the prior 12 months were included in the analyses. The number of facilities per month ranged from 6,779-7,220 and the total number of patients per year ranged from 115,929-117,942.

Public reporting of this measure on DFC or in the ESRD QIP would be restricted to facilities with at least 1 expected modality switch throughout the reporting period for the measure. We have applied this restriction to all the reliability and validity testing reported here.

[Response Ends]

2a.06. Identify the number and descriptive characteristics of patients included in the analysis (e.g., age, sex, race, diagnosis), separated by level of analysis and data source; if a sample was used, describe how patients were selected for inclusion in the sample.

If there is a minimum case count used for testing, that minimum must be reflected in the specifications.

[Response Begins]

Baseline Patient Characteristics	*
BMI < 18.5	9,810 (3.1%)
18.5 ≤ BMI < 25	87,078 (28%)
25≤ BMI < 30	87,624 (28%)
BMI≥30	131,870 (42%)
Gender	*
Female	132,354 (42%)
Male	184,028 (58%)
Age Categories	*
18 < age <= 25	2,809 (0.9%)
25 < age <= 35	10,822 (3.4%)

Baseline Patient Characteristics	*
35 < age <= 45	21,533 (6.8%)
45 < age <= 55	45,781 (14%)
55 < age <= 65	77,920 (25%)
65 < age <= 75	87,094 (28%)
75 < age <= 85	56,799 (18%)
age > 85	13,624 (4.3%)
Race	*
White	210,902 (67%)
Native American/Alaskan Native	3,170 (1.0%)
Asian/Pacific Islander	17,045 (5.4%)
Black	84,388 (27%)
Other race	877 (0.3%)
Ethnicity	*
Hispanic	49,270 (16%)
Non-Hispanic	267,103 (84%)
Unknown	9 (<0.1%)
Medicare Status	*
Dual Eligible	64,264(20.3%)
Medicare Primary Only	93,259 (29.5%)
Medicare Secondary	34,591(10.9%)
Medicare Advantage/HMO	74,825 (23.7%)
Other	49,443 (15.6%)
Cause of ESRD	*
Diabetes	157,496 (50%)
Non-Diabetes	158,886 (50%)

Baseline Paient Characteristics

*This cell is intentionally left blank under the table in this question in order for it to be 508-compliant.

[Response Ends]

2a.07. If there are differences in the data or sample used for different aspects of testing (e.g., reliability, validity, exclusions, risk adjustment), identify how the data or sample are different for each aspect of testing.

[Response Begins]

N/A

[Response Ends]

2a.08. List the social risk factors that were available and analyzed.

For example, patient-reported data (e.g., income, education, language), proxy variables when social risk data are not collected from each patient (e.g. census tract), or patient community characteristics (e.g. percent vacant housing, crime rate) which do not have to be a proxy for patient-level data.

[Response Begins]

Patient level:

- Employment status 6 months prior to ESRD
- Sex
- Race
- Ethnicity
- Medicare coverage*

**Assessed at a specific time point (e.g., at a home modality switch event). The final variable for Medicare coverage in the model was recoded as:*

1. Medicare as primary and Medicaid (dual eligible)

2. Non-dual Eligible

Area level:

ZIP code level – Area Deprivation Index (ADI) from Census data (2015). Based on patient zip-code.

[Response Ends]

Note: If accuracy/correctness (validity) of data elements was empirically tested, separate reliability testing of data elements is not required – in 2a.07 check patient or encounter-level data; in 2a.08 enter "see validity testing section of data elements"; and enter "N/A" for 2a.09 and 2a.10.

2a.09. Select the level of reliability testing conducted.

Choose one or both levels.

[Response Begins]

Accountable Entity Level (e.g., signal-to-noise analysis)

[Response Ends]

2a.10. For each level of reliability testing checked above, describe the method of reliability testing and what it tests.

Describe the steps—do not just name a method; what type of error does it test; what statistical analysis was used.

[Response Begins]

The reliability of the SMoSR was assessed using data from adult ESRD dialysis patients during 2016-2019. 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 SMoSR, however, is not a simple average and instead estimates the IUR using a bootstrap approach, which utilizes a resampling procedure 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 SMoSR for N facilities. For each facility, we randomly draw B bootstrap samples of subjects with replacement, each having the same number of subjects as the facility. Our numerical experiments reveal that B=100 is sufficient to reach estimation stability. That is, if the i^{th} facility has n_i subjects, randomly draw with replacement n_i subjects from those in the same facility, find the corresponding $SMoSR_i$ and repeat the procedure B (say, 100) times. Thus, for the i^{th} facility, we have obtained 100 bootstrapped SMoSRs, $T_{i1}^*, \ldots, T_{i100}^*$. Let S_i^* be the sample variance of this bootstrap sample for facility i, given by

$$s_{t,w}^2 = \frac{\sum_{i=1}^{N}[(n_i-1)S_i^{*2}]}{\sum_{i=1}^{N}(n_i-1)}$$

which is a bootstrap estimate of the within-facility variance in the SMoSR, namely, $\sigma_{(t,w)}^2$. Calling on formulas from the one-way analysis of variance, an estimate of the overall variance of T_i is

$$s_t^2 = \frac{1}{n'(N-1)}\sum_{i=1}^{N} n_i(T_i-\overline{T})^2$$

where

$$\overline{T} = \sum n_i T_i \Big/ \sum n_i$$

is the overall mean of the observed SMoSR and

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

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

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

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

To assess more directly the value of the measure in identifying providers with extreme outcomes, we also computed an additional metric, termed the profile IUR (PIUR). This was to address the challenge that the IUR could be small in the situation where many providers have outcomes around the national norm, even though the measure may still be able to identify facilities with extreme outcomes. The PIUR, based on the measure's ability to consistently flag extreme providers, was computed with a two-step approach: first, we evaluated the ability of a measure to consistently profile facilities with extreme outcomes; second, we mapped this reflagging ability to an IUR value computed by assuming no outlier facilities. This resulting value was defined to be the PIUR. The difference between the PIUR and the IUR indicates the extent to which the measure identifies outliers.

The SMoSR calculation only included facilities with at least 1 expected modality switch.

[Response Ends]

2a.11. For each level of reliability testing checked above, what were the statistical results from reliability testing?

For example, provide the percent agreement and kappa for the critical data elements, or distribution of reliability statistics from a signal-to-noise analysis. For score-level reliability testing, when using a signal-to-noise analysis, more than just one overall statistic should be reported (i.e., to demonstrate variation in reliability across providers). If a particular method yields only one statistic, this should be explained. In addition, reporting of results stratified by sample size is preferred (pg. 18, NQF Measure Evaluation Criteria).

[Response Begins]

Overall, we found that IUR for SMoSR has a value of 0.605, which indicates that over 60% of the variation in the SMoSR can be attributed to the between-facility differences and less than 40% to the within-facility variation.

The PIUR is 0.606.

[Response Ends]

2a.12. Interpret the results, in terms of how they demonstrate reliability.

(In other words, what do the results mean and what are the norms for the test conducted?)

[Response Begins]

The IUR is moderate and indicates that the measure can detect differences in performance scores across facilities.

As noted above, the PIUR measures reliability in terms of reflagging rates but is placed on the same scale as IUR. A PIUR that is larger than the IUR indicates that the measure has a higher reliability for identifying extreme values. In this case, the IUR and PIUR are nearly the same, so the IUR also is descriptive of the measures usefulness in identifying extreme values.

[Response Ends]

2b. Validity

2b.01. Select the level of validity testing that was conducted.

[Response Begins]

Accountable Entity Level (e.g. hospitals, clinicians)

Empirical validity testing

[Response Ends]

2b.02. For each level of testing checked above, describe the method of validity testing and what it tests.

Describe the steps—do not just name a method; what was tested, e.g., accuracy of data elements compared to authoritative source, relationship to another measure as expected; what statistical analysis was used.

[Response Begins]

Validity of the Standardized Modality Switch Ratio was assessed using several different statistical tests to examine the relationship with other facility level quality measures: Standardized Mortality Ratio (SMR), First-Year Standardized Mortality Ratio (FYSMR), Standardized Hospitalization Ratio (SHR), Standardized Waitlist Ratio-Incident Dialysis Patients (SWR), ICH-CAHPS "Providing information to patients", and the percentage of home dialysis patients at the facility.

Spearman's rho Correlations with Quality Outcome Performance Measures:

We started by calculating Spearman's rho coefficient to examine the correlation of SMoSR with SMR, FYSMR, SHR, and SWR. Spearman's correlation coefficient, which is a rank-based correlation metric, was chosen for its robustness against potential extreme providers and tied providers. The peer-reviewed literature is mixed in regard to whether home dialysis compared to in-center dialysis offers better survival or lower hospitalization rates. Therefore, we hypothesized no or weak correlations of SMoSR with SMR, FYSMR, and SHR. However, facility processes of care that support robust modality education should result in higher referral for transplant evaluation and subsequent waitlisting. Therefore, we hypothesized a positive correlation between SMoSR and SWR. Table 1 reports the estimated Spearman's rho correlations.

Gamma Tests for Concordance Analysis with Performance Classification:

Next, we performed gamma tests to examine the concordance of facility level SMoSR flagging classifications ("Better than Expected", "As Expected", and "Worse than Expected") with 2019 SWR. The choice of gamma tests in the analysis is due to the fact that these performance categories are naturally ordered in a descending order.

A positive Gamma coefficient would indicate a concordance in flagging categories between SMoSR and an existing performance measure. In contrast, a negative Gamma signifies a discordant relationship. The null hypothesis of Gamma=0 is set up to test for a significant correlation. The higher a Gamma value the stronger the relationship. We hypothesized that there would be moderate agreement in facility classification of performance between the SMoSR and the first year SWR. The estimated magnitude of concordance is provided in Table 2.

Association with patient reported outcomes: ICH-CAHPS "Providing information to patients":

The In-Center Hemodialysis Consumer Assessment of Healthcare Provider and Systems (ICH-CAHPS)[1] is a patient reported experience of care survey to measure in-center hemodialysis patients' perspectives on the care they receive at dialysis facilities. This measure is reported on Dialysis Facility Care Compare. We computed a Pearson correlation (rho) to assess the association between the ICH-CAHPS mean scores for the 9 question composite measure on "providing information to patients"[1] and SMoSR performance classifications of "better than expected", "as expected", and "worse than expected."

Collectively the ICH-CAHPS linearized top box score for "providing information" indicates how well the facility is doing providing information on safety as well as all renal replacement modalities, including home dialysis and transplant. Since this facility process of modality education is a critical step for many patients to understand their treatment choices, we expect a higher proportion of patients reporting "yes" on facilities "always providing information" will be associated with a better performance classification on SMoSR. Please see Table 3 below for this association and the Pearson's correlation r statistic.

Association between the percentage of home dialysis patients and performance on SMoSR:

We computed a Pearson correlation rho to assess the association between the different SMoSR performance classifications and the percentage of home dialysis patients at a facility. The proportion of home dialysis patients at a facility reflects the processes that are in place to provide effective modality education and then

facilitate a transfer from in-center to home dialysis. We expect a better SMoSR performance classification to be associated with a higher percentage of patients on home dialysis at a facility. Table 4 reports these results and the Pearson correlation r statistic.

Two-part Semi-continuous Model:

A challenge with the analysis for the association between SMoSR and the percentage of home dialysis patients at a facility is that some facilities have no home program resulting in zero patients on home dialysis. This cluster of "zero-patient" facilities will distort the correlation calculation due to the significant amount of ties. One option is to delete these facilities from the calculation. However, such an approach would then be based on a selective sub-sample which may introduce bias. To avoid this, we used a two-part semi-continuous regression model that accommodates data that have both a spike at zero and continuous values over the nonzero part (Atchison 1995). In the first part, we used a logistic regression model to predict the propensity of observing facilities with zero (vs. nonzero) percentage of home dialysis patients as a function of the SMoSR, adjusted for a set of facility characteristics. For the second part of the model, a linear regression is fit only among the subset of facilities with non-zero number of home dialysis patients using SMoSR as the predictor for the percentage of home dialysis patients. We adjusted for the same set of facility characteristics as the binary part. The two models are connected formally through a mixture structure, where the mixing proportion is estimated from the data.

For the logistic model, we expect a higher SMoSR value to be associated with lower odds of facilities having zero home dialysis patients; whereas for the linear model, we expect a positive association between SMoSR and the percentage of home dialysis patients. These results are presented in Table 5 below.

In addition to the above mentioned statistical tests, the validity of the measure is also based on face validity. The SMoSR was reviewed by a TEP in 2021 which supported the measure construct and provided input on the SMoSR risk adjustment and exclusion methodology.

References:

Aitchison J. On the distribution of a positive random variable having a discrete probability mass at the origin. Journal of The American Statistical Association 1955; 50: 901–908.

University of Michigan Kidney Epidemiology and Cost Center. Effective Availability and Utilization of Home Dialysis Technical Expert Panel Summary Report, Prepared for The Centers for Medicare and Medicaid Services. June, 2021.

[1] Please see https://ichcahps.org/Survey-and-Protocols for the list of questions included in the composite measure which include: "In the last 12 months, did either your kidney doctors or dialysis center staff talk to you about peritoneal dialysis?" and "In the last 12 months, were you as involved as much as you wanted in choosing the treatment that is right for you?"

[Response Ends]

2b.03. Provide the statistical results from validity testing.

Examples may include correlations or t-test results.

[Response Begins]

Table 1. Spearman Correlation between SMoSR and other Quality Measures, 2016 - 2019

Measure	Spearman's rho	p-value
SMR (2016-2019)	0.030	0.038
FYSMR(2016-2019)	-0.030	0.022

Measure	Spearman's rho	p-value
SHR (2019)	-0.060	<0.0001
SWR (2016-2019)	0.120	<0.0001

Spearman Correlation between SMoSR and other Quality Measures, 2016 - 2019

Table 2: Concordance of SWR and SMoSR (Gamma: 0.29; p<0.0001)

*	*	SWR	*	*
Facility Performance	Worse than Expected	As Expected	Better than Expected	**Total**
SMoSR	*	*	*	*
Worse than Expected	46 (1.2%)	187 (4.7%)	21 (0.5%)	254 (6.4%)
As Expected	174 (4.4%)	2,980 (75%)	191 (4.8%)	3,345 (85%)
Better than Expected	14 (0.4%)	314 (7.9%)	28 (0.7%)	356 (9.0%)
Total	234 (5.9%)	3,481 (88%)	240 (6.1%)	3,955 (100%)

Concordance of SWR and SMoSR (Gamma: 0.29; p<0.0001)

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Table 3: Association of facility performance on SMoSR with ICH-CAHPS score - The Linearized Top Box Score of "Providing Information To Patients" (Pearson's r = 0.191)

*	**SMoSR**	*	*
Facility Performance	Worse than Expected	As Expected	Better than Expected
The Linearized Score Of Providing Information To Patients	77.60	80.77	82.60

Association of facility performance on SMoSR with ICH-CAHPS score - The Linearized Top Box Score of "Providing Information To Patients" (Pearson's r = 0.191)

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Table 4: Association of facility performance on SMoSR with percentage of Patients on Home Dialysis Modality (Pearson's r = 0.398)

*	**SMoSR**	*	*
Facility Performance	Worse than Expected	As Expected	Better than Expected
Percentage of Home dialysis patients at the end of 2019	9.50%	17.55%	26.96%

Association of facility performance on SMoSR with percentage of Patients on Home Dialysis Modality (Pearson's r = 0.398)

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Table 5: Association between SMoSR and Percentage of Home Dialysis Patients – Two Part Semi-Continuous Model

*	Logistic Regression	*	*	Linear Regression	*	*
Covariates	**OR**	**95% CI**	**p-value**	**Coefficient**	**95% CI[1]**	**p-value**
SMoSR	0.7	0.62, 0.80	<0.001	2.9	2.6, 3.2	<0.001

Association between SMoSR and Percentage of Home Dialysis Patients – Two Part Semi-Continuous Model

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[Response Ends]

2b.04. Provide your interpretation of the results in terms of demonstrating validity. (i.e., what do the results mean and what are the norms for the test conducted?)

[Response Begins]

Table 1 reports the results of the Spearman correlations testing the association between SMoSR and the SMR, FYSMR, SHR, and SWR. SMoSR is associated with SWR (Spearman's rho=0.12, p<.0001), in the expected direction. This suggests that facilities that do well facilitating education on transplant that results in patient waitlisting within the first year, are also performing well providing effective education on home dialysis that results in switches from in-center to home dialysis within the first year. As expected, all other associations between SMoSR and SMR, FYSMR, and SHR were very weak (Table 1) based on the Spearman correlation coefficients. This lack of association is supported by the peer-reviewed literature that has failed to demonstrate a clear relationship between dialysis modality and hospitalization or mortality.

Due to the positive correlation between SMoSR and SWR found in Table 1, we expect moderate agreement in facility classification of performance between the SMoSR and first year SWR. The positive Gamma coefficient 0.29 was statistically significant (p<0.0001) indicating that facilities that perform significantly better helping patients switch to home dialysis also do significantly better in helping patients in the referral and waitlisting process for transplant.

Facilities that have processes in place to support effective modality education for kidney failure are more likely to have both higher rates of transplant waitlisting as well as higher switch rates to home dialysis. Therefore, as hypothesized, we found concordance in flagging of facility performance based on the positive gamma values for this test. The Gamma statistic reflects moderate agreement in facility performance categories.

For ICH CAHPS (Table 3), as hypothesized, facilities with a better SmoSR performance have a higher ICH-CAHPS score for providing information to patients. The correlation was only moderate likely due to the ICH-CAHPS composite score also containing questions about general safety in the dialysis clinic that are not specific to modality education.

The average percentage of patients on home dialysis is 9.50%, 17.55% and 26.96% among facilities with the SMoSR classifications "Worse than Expected", "As Expected" and "Better than Expected", respectively. In addition, we observed a moderate correlation (Pearson's rho = 0.398). As hypothesized, among facilities with patients on a home dialysis modality, a better modality switch performance category is associated with a

higher proportion of patients on home dialysis as of the end of 2019 (Table 4), which indicates these facilities provided more effective modality education that resulted in a switch to home dialysis. Because this analysis was only on a subset of facilities, those that had at least one patient on a home modality, we estimated a model on the full population of facilities that takes into account whether facilities have 0 or >0 home dialysis patients. Table 5 has findings from two parts of the zero-inflated semi-continuous model that are consistent. The logistic regression part asserts that each unit increase in SMoSR is associated with a 30% decrease in odds of observing a facility with zero home-dialysis patients (p-value < 0.001). The linear regression part of the model indicates that for facilities with non-zero number of home dialysis patients, the proportion of home dialysis patients is positively associated with the SMoSR (beta coefficient=2.9, p<.0001) reaffirming the earlier findings in Table 4. As a bottomline, facilities providing more effective modality switch education have higher SMoSRs.

[Response Ends]

2b.05. Describe the method for determining if statistically significant and clinically/practically meaningful differences in performance measure scores among the measured entities can be identified.

Describe the steps—do not just name a method; what statistical analysis was used? Do not just repeat the information provided in Importance to Measure and Report: Gap in Care/Disparities.

[Response Begins]

The p-value for a given facility is a measure of the strength of the evidence against the hypothesis that the modality switch rate for this facility is identical to that seen nationally overall, having adjusted for the patient mix. Thus, the p-value is the probability that the facility's SMoSR would deviate from 1.00 (national rate) by at least as much as the facility's observed SMoSR. In practice, the p-value is computed using a Poisson approximation under which the distribution of the number of switches to a home modality in the facility is Poisson with a mean value equal to E, the expected number of switches as computed from the Cox model. Accordingly, if the observed number, O, is greater than E, then p-value = 2 * Pr(X>=O) where X has a Poisson distribution with mean E. Similarly, if O<E, the p-value = 2 * Pr(X <=O) where X has a Poisson distribution with mean E.

If the facility SMoSR is less than 1.00 and statistically significant (p<0.05), the classification is "Worse than Expected". This classification is based on the measure ratio, not the rate. If the ratio is greater than 1.00 and statistically significant (p<0.05), the classification is "Better than Expected". Otherwise, the classification is "As Expected". Please note that the facility is not included here if the facility had less than 1 expected modality switch during the reporting period.

[Response Ends]

2b.06. Describe the statistical results from testing the ability to identify statistically significant and/or clinically/practically meaningful differences in performance measure scores across measured entities.

Examples may include number and percentage of entities with scores that were statistically significantly different from mean or some benchmark, different from expected; how was meaningful difference defined.

[Response Begins]

Table 6: Proportion of facilities with statistically significant differences

Better than Expected	As Expected	Worse than Expected	Total
465 (7.7%)	5,313 (88%)	261 (4.3%)	6039

Proportion of facilities with statistically significant differences

[Response Ends]

2b.07. Provide your interpretation of the results in terms of demonstrating the ability to identify statistically significant and/or clinically/practically meaningful differences in performance across measured entities.

In other words, what do the results mean in terms of statistical and meaningful differences?

[Response Begins]

Facilities are flagged if they have outcomes that are extreme when compared to the variation in national modality switch rates adjusted for patient case-mix.

Across all facilities, for the 2016-2019 SMoSR, the majority of facilities had modality switch scores that were "As Expected." Approximately 7.7% of facilities had a SMoSR that was "Better than expected," while 4.3% of facilities had a SMoSR that was "Worse than expected."

These results suggest that the SMoSR is able to detect statistically significant meaningful differences in performance, specifically facilities that do much better or worse than the national average across all facilities.

[Response Ends]

2b.08. Describe the method of testing conducted to identify the extent and distribution of missing data (or non-response) and demonstrate that performance results are not biased due to systematic missing data (or differences between responders and non-responders). Include how the specified handling of missing data minimizes bias.

Describe the steps—do not just name a method; what statistical analysis was used.

[Response Begins]

All ESRD patients are required to have a Form CMS 2728 submitted to CMS regardless of the patient's Medicare status. The 2728 certifies the patient has ESRD. The CMS 2728 data are in CROWNWeb. All patients must have a Medical Evidence Form (Form CMS-2728) to be included in the Standardized Modality Switch Ratio. The measure includes all those patients regardless of missing data for the primary cause of ESRD or BMI. Missing data occurs rarely. We report the frequency of missing for the data below (patient level).

- Missing primary cause of ESRD on Form CMS-2728
- Missing BMI from the Form CMS-2728 – see above. This is part of the required fields in the 2728.

[Response Ends]

2b.09. Provide the overall frequency of missing data, the distribution of missing data across providers, and the results from testing related to missing data.

For example, provide results of sensitivity analysis of the effect of various rules for missing data/non-response. If no empirical sensitivity analysis was conducted, identify the approaches for handling missing data that were considered and benefits and drawbacks of each).

[Response Begins]

Summary findings:

Patients with missing primary cause of ESRD on Form CMS-2728 is 0.02% and missing BMI on 2728 is 0.31% of the all patients.

Table 7. Frequency of missing data elements, 2018 data

Data Element	Missing (%)
Patients with missing primary cause of ESRD on Form CMS-2728	0.02%
Patient without BMI reported on Form CMS-2728	0.31%

Frequency of missing data elements, 2018 data

[Response Ends]

2b.10. Provide your interpretation of the results, in terms of demonstrating that performance results are not biased due to systematic missing data (or differences between responders and non-responders), and how the specified handling of missing data minimizes bias.

In other words, what do the results mean in terms of supporting the selected approach for missing data and what are the norms for the test conducted; if no empirical analysis was conducted, justify the selected approach for missing data.

[Response Begins]

There is a very low frequency of patients with missing primary cause of ESRD and BMI from the CMS form 2728. Missing primary cause of ESRD was adjusted through inclusion of a missing indicator in the regression model, and missing BMI was included as BMI 30+ category (the group with the highest frequency). Given such a small percent of missing (0.31% for BMI and 0.02% for primary cause of ESRD on CMS 2728 form), the impact of missing data on performance scores is negligible and unlikely to be a source of bias in the measure.

[Response Ends]

Note: This item is directed to measures that are risk-adjusted (with or without social risk factors) OR to measures with more than one set of specifications/instructions (e.g., one set of specifications for how to identify and compute the measure from medical record abstraction and a different set of specifications for claims or eCQMs). It does not apply to measures that use more than one source of data in one set of specifications/instructions (e.g., claims data to identify the denominator and medical record abstraction for the numerator). Comparability is not required when comparing performance scores with and without social risk factors in the risk adjustment model. However, if comparability is not demonstrated for measures with more than one set of specifications/instructions, the different specifications (e.g., for medical records vs. claims) should be submitted as separate measures.

2b.11. Indicate whether there is more than one set of specifications for this measure.

[Response Begins]

No, there is only one set of specifications for this measure

[Response Ends]

2b.12. Describe the method of testing conducted to compare performance scores for the same entities across the different data sources/specifications.

Describe the steps—do not just name a method. Indicate what statistical analysis was used.

[Response Begins]

[Response Ends]

2b.13. Provide the statistical results from testing comparability of performance scores for the same entities when using different data sources/specifications.

Examples may include correlation, and/or rank order.

[Response Begins]

[Response Ends]

2b.14. Provide your interpretation of the results in terms of the differences in performance measure scores for the same entities across the different data sources/specifications.

In other words, what do the results mean and what are the norms for the test conducted.

[Response Begins]

[Response Ends]

2b.15. Indicate whether the measure uses exclusions.

[Response Begins]

Yes, the measure uses exclusions.

[Response Ends]

2b.16. Describe the method of testing exclusions and what was tested.

Describe the steps—do not just name a method; what was tested, e.g., whether exclusions affect overall performance scores; what statistical analysis was used?

[Response Begins]

The following exclusions are applied to the denominator:

- Patients time at risk under hospice care

- Nursing home patients on home hemodialysis

We calculate the number and percent of patient-time at risk and unique patients for the current (base) measure (exclusions applied) and without the exclusions.

We also compare facility performance classification between SMoSR with and without the exclusions applied. See section 2b.05 for a description of the method used to calculate the p-value for facility flagging and how facilities are classified.

We do not use this exclusion criteria for this measure.

No edits have been made to this response.

[Response Ends]

2b.17. Provide the statistical results from testing exclusions.

Include overall number and percentage of individuals excluded, frequency distribution of exclusions across measured entities, and impact on performance measure scores.

[Response Begins]

The following tables show the percent of patient-year at risk and the number of unique patients excluded as a result of the above mentioned exclusion strategy. For more details regarding the methodology of the denominator exclusions, please refer to section sp.17. The sensitivity models with and without each exclusion are compared.

Table 8: Percent of patient-year at risk excluded, 2016-2019 data

Exclusion	Before Exclusion	After Exclusion	Percent
Nursing Home	256,100	255,662.7	0.170%
Hospice care	257,500.4	255,662.7	0.732%

Percent of patient-year at risk excluded, 2016-2019 data

Table 9: Number and percent of unique patients excluded, 2016-2019 data

Exclusion	Before Exclusion	After Exclusion	Percent
Nursing Home	317,985	316,382	0.504%
Hospice	317,935	316,382	0.488%

Number and percent of unique patients excluded, 2016-2019 data

Table 10 Comparing sensitivity models with and without the hospice exclusion, 2016-2019 data

*	**Current SMoSR**	*	*	*
Facility Performance	Better than expected	As expected	Worse than expected	**Total**

*	**Current SMoSR**	*	*	*
SMoSR without the hospice exclusion	*	*	*	*
Better than expected	462 (7.7%)	6 (<0.1%)	0 (0%)	468 (7.7%)
As expected	3 (<0.1%)	5,302 (88%)	1 (<0.1%)	5,306 (88%)
Worse than expected	0 (0%)	5 (<0.1%)	260 (4.3%)	265 (4.4%)
Total	465 (7.7%)	5,313 (88%)	261 (4.3%)	6,039 (100%)

Comparing sensitivity models with and without the hospice exclusion, 2016-2019 data

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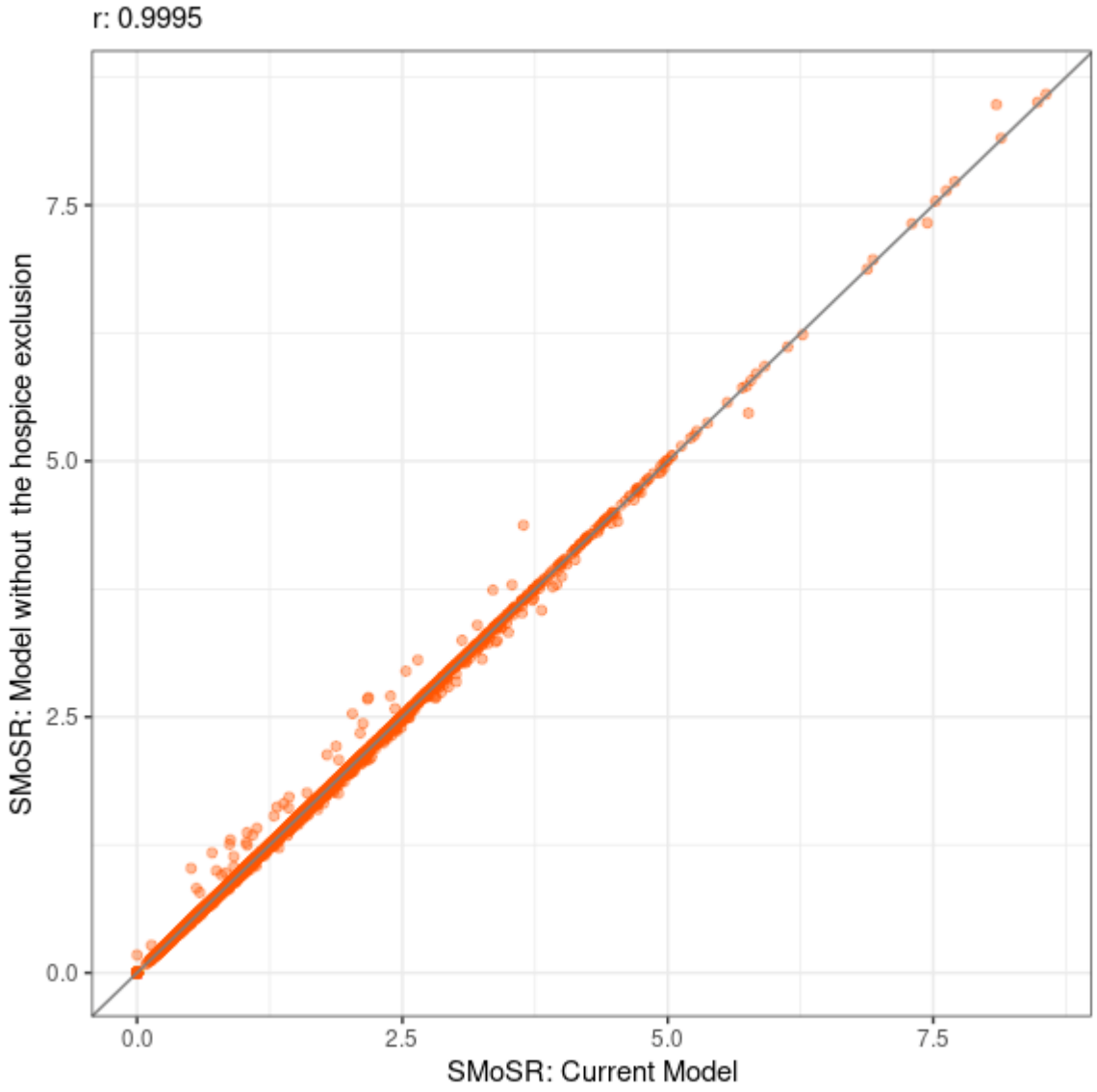
Figure 1: Comparing the SMoSR models with and without excluding the time at risk for hospice stays



Comparing the SMoSR models with and without excluding the time at risk for hospice stays, 15 (<0.2%) facilities changed performance categories. After the exclusion criterion applied, 7(<0.1%) facilities moved to a

lower performance category, and 8 (<0.1%) facilities moved to a higher performance category. The SMoSR measure with and without the hospice exclusion are highly correlated (r=0.999).

Table 11: Comparing sensitivity models with and without the nursing home exclusion, 2016-2019 data

*	**Current SMoSR**	*	*	*
Facility Performance	**Better than expected**	**As expected**	**Worse than expected**	**Total**
SMoSR without the nursing home exclusion	*	*	*	*
Better than expected	432 (7.2%)	17 (0.3%)	1 (<0.1%)	450 (7.5%)
As expected	33 (0.5%)	5,264 (87%)	4 (<0.1%)	5,301 (88%)
Worse than expected	0 (0%)	32 (0.5%)	256 (4.2%)	288 (4.8%)
Total	465 (7.7%)	5,313 (88%)	261 (4.3%)	6,039 (100%)

Comparing sensitivity models with and without the nursing home exclusion, 2016-2019 data

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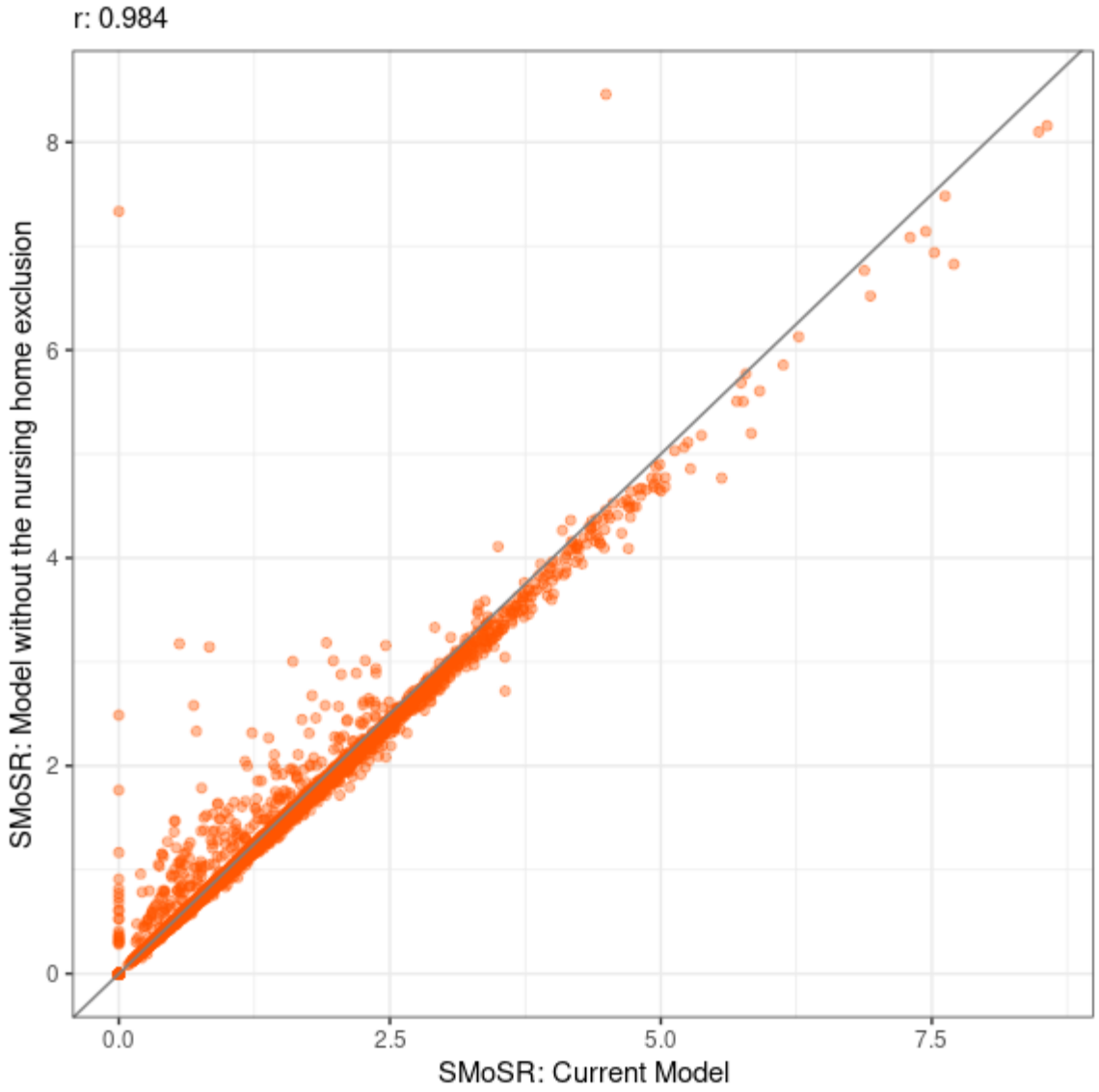
Figure 2: Comparing the SMoSR models with and without excluding nursing home patients that switched to home hemodialysis

hemodialysis



Comparing the SMoSR models with and without excluding nursing home patients that switched to home hemodialysis, 87 (1.5%) facilities changed performance categories. After the exclusion criterion applied, 65 (1.0%) facilities moved to a higher performance category, and 22 (0.5%) facilities moved to a lower performance category. SMoSR with and without the exclusion of nursing home patients that switched to home hemodialysis were highly correlated (r=0.984).

[Response Ends]

2b.18. Provide your interpretation of the results, in terms of demonstrating that exclusions are needed to prevent unfair distortion of performance results.

In other words, the value outweighs the burden of increased data collection and analysis. Note: If patient preference is an exclusion, the measure must be specified so that the effect on the performance score is transparent, e.g., scores with and without exclusion.

[Response Begins]

These analyses indicate that excluding time at risk at hospice stay had minimal or no effect on facility performance on the SMoSR. Similarly, excluding nursing home patients that switch to home hemodialysis had minimal or no effect on facility performance.

The exclusions are needed because the number of patients under hospice care or nursing home patients that switch to home hemodialysis are not distributed evenly across all facilities. While the numbers are generally small it would not be appropriate to include patients under hospice care that may switch to home dialysis as part of end of life care at home.

Nursing home patients that switch to home hemodialysis do so typically as a result of an administrative decision by the nursing home to deliver "home hemodialysis" in the nursing home. This does not reflect shared decision making by the patient.

[Response Ends]

2b.19. Check all methods used to address risk factors.

[Response Begins]

Statistical risk model with risk factors (specify number of risk factors)

[Statistical risk model with risk factors (specify number of risk factors) Please Explain]

18

[Response Ends]

2b.20. If using statistical risk models, provide detailed risk model specifications, including the risk model method, risk factors, risk factor data sources, coefficients, equations, codes with descriptors, and definitions.

[Response Begins]

A two-stage Cox model is used with the first stage being a patient model stratified by facility to avoid bias caused by different covariate distributions across facilities. In this model, covariates are taken to act multiplicatively on the modality switch rate and the adjustment model is fitted with facility defining strata in order to provide valid estimates even if the distribution of adjustment variables differs across facilities. Relevant references are Cox (1972) and Kalbfleisch and Prentice (2002). All analyses are performed using SAS.

The denominator of SMoSR for a facility is the expected number of switches from the patient-records meeting the inclusion criteria, based on the number of days attributed to that facility. Specifically, the expectation is calculated using a two-stage model. At Stage 1, we fit a Cox model (Cox, 1972) stratified by facility and adjusted for patient age, diabetes as cause of ESRD, patient comorbidities at ESRD incidence, calendar year, and body mass index (BMI) at incidence. This stratified model allows each facility to have a distinct baseline survival function while retaining the same regression coefficients of all the adjusters across all the facilities. Stratification by facility avoids estimating facility effects directly and also reduces computational burden. A linear predictor using the estimates of regression coefficients will be computed for each patient and will be used as the offset term in the Stage 2 modeling. At Stage 2, we fit an unstratified Cox model, which includes the offset term from Stage 1 model. The baseline hazard or survival function of this model has national norm interpretations. With the fitted model at Stage 2, we compute the expected probability of modality switch for each patient based on the aforementioned adjusters and the number of days assigned to a facility. The denominator of SMoSR for a facility is then the summation of expected probabilities of modality switch from all the patients assigned to that facility.

adjusted for patient age, diabetes as cause of ESRD, patient comorbidities at ESRD incidence, calendar year, and body mass index (BMI) at incidence. This stratified model allows each facility to have a distinct baseline survival function while retaining the same regression coefficients of all the adjusters across all the facilities. Stratification by facility avoids estimating facility effects directly and also reduces computational burden. A linear predictor using the estimates of regression coefficients will be computed for each patient and will be used as the offset term in the Stage 2 modeling. At Stage 2, we fit an unstratified Cox model, which includes the offset term from Stage 1 model. The baseline hazard or survival function of this model has national norm interpretations. With the fitted model at Stage 2, we compute the expected probability of modality switch for each patient based on the aforementioned adjusters and the number of days assigned to a facility. The denominator of SMoSR for a facility is then the summation of expected probabilities of modality switch from all the patients assigned to that facility.

The patient characteristics included in the stage 1 model as covariates are:

- Age: Age is included as a piecewise continuous variable with different coefficients based on whether the patient is 18-25 years old, 26-35 years old, 36-45 years old, 46-55 years old, 56-65 years old, 66-75 years old, 76-85 years old, or 85+ years old.
- Diabetes as cause of ESRD
- BMI at ESRD incidence:
    - BMI < 18.5
    - 18.5 ≤ BMI < 25
    - 25≤ BMI < 30
    - BMI ≥30
- Comorbidities at ESRD incidence:
    - Atherosclerotic heart disease
    - Other cardiac disease
    - Diabetes other than as primary cause of ESRD (all types including diabetic retinopathy)
    - Congestive heart failure
    - Inability to ambulate
    - Chronic obstructive pulmonary disease
    - Inability to transfer
    - Malignant neoplasm, cancer
    - Peripheral vascular disease
    - Cerebrovascular disease, CVA, TIA
    - Tobacco use (current smoker)
    - Alcohol dependence
    - Drug dependence
    - At least one of the comorbidities listed
- Calendar year

In general, adjustment factors for the SMoSR were selected based on several considerations, specifically clinical criteria, technical panel expert input, and data availability. We began with a large set of patient characteristics, including demographics, comorbidities at ESRD incidence, and other characteristics. Factors considered appropriate were then investigated with statistical models to determine if they were related to modality switch. Factors related to the SMoSR were also evaluated for face validity before being included. Finally, SDS/SES factors were evaluated based on appropriateness (whether related to disparities in care), and empirical association with the outcome. Based on input from the 2021 TEP, and because of known disparities based on race, ethnicity, sex, and SES, these factors were not included in the final model.

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

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

2b.22. Select all applicable resources and methods used to develop the conceptual model of how social risk impacts this outcome.

[Response Begins]

Published literature

Internal data analysis

Other (specify)

[Other (specify) Please Explain]

Input from the 2021 Technical Expert Panel. The TEP consensus was there are known disparities by SDS/SES and uptake of home dialysis. Adjusting for these social risk factors could potentially further disadvantage patients based on their race, ethnicity, or lack of SES-based resources.

[Response Ends]

2b.23. Describe the conceptual and statistical methods and criteria used to test and select patient-level risk factors (e.g., clinical factors, social risk factors) used in the statistical risk model or for stratification by risk.

Please be sure to address the following: potential factors identified in the literature and/or expert panel; regression analysis; statistical significance of p<0.10 or other statistical tests; correlation of x or higher. Patient factors should be present at the start of care, if applicable. Also discuss any "ordering" of risk factor inclusion; note whether social risk factors are added after all clinical factors. Discuss any considerations regarding data sources (e.g., availability, specificity).

[Response Begins]

The conceptual model was developed from published peer reviewed literature, our own internal data descriptive analyses based on available data, and feedback from the 2021 Home Dialysis Technical Expert panel. The starting point was identifying social demographic factors associated with poorer outcomes of the measure, specifically lower uptake in home dialysis modalities (e.g., King 2020; Mehrotra 2016; Shen 2020, 2019; Perez 2018; Thorsness 2021; Walker 2010). While this literature is observational, it provides insight into patient level demographic characteristics associated with uptake of home dialysis, specifically race, ethnicity, dual-eligible (Medicare-Medicaid) status, employment status and SES. These social risk factors are present at the start of care but also reflect sources of potential disparities (Shen 2020; Mehrotra, 2016; King, 2020). For example, uptake of home dialysis is lower among Black patients and patients of Hispanic ethnicity (Shen 2020; Mehrotra 2016). For Black patients, this may be due in part to lack of sufficient education on modality choices (King 2020). Patients that are uninsured or on Medicaid also have been found to be less likely to start on or stay on peritoneal dialysis (Perez 2018). One limitation of the observational studies is that they cannot determine if education is causally associated with modality selection or whether home modality selection is confounded by other unmeasured factors.

Finally, feedback from the TEP confirmed what is reported in the peer reviewed literature, including lower rates of home dialysis uptake among Black and Hispanic patients, and patients with lower SES, particularly in the first year of chronic dialysis.

For additional information, see 2b.20 above for a description of selection of patient risk factors.

Selection of specific social risk factors

Patient level social risk factors available for testing:

- Employment status 6 months prior to ESRD (CMS Form 2728)
- Sex, race, ethnicity (CMS Enrollment database; CMS Form 2728)
- Medicare coverage* (CMS Enrollment database)

determine if education is causally associated with modality selection or whether home modality selection is confounded by other unmeasured factors.

Finally, feedback from the TEP confirmed what is reported in the peer reviewed literature, including lower rates of home dialysis uptake among Black and Hispanic patients, and patients with lower SES, particularly in the first year of chronic dialysis.

For additional information, see 2b.20 above for a description of selection of patient risk factors.

Selection of specific social risk factors

Patient level social risk factors available for testing:

- Employment status 6 months prior to ESRD (CMS Form 2728)
- Sex, race, ethnicity (CMS Enrollment database; CMS Form 2728)
- Medicare coverage* (CMS Enrollment database)
    - *Assessed at a specific time point (e.g., at a home modality switch event). The final variable for Medicare coverage in the model was recoded as:
    - 1. Medicare as primary and Medicaid (dual eligible)
    - 2. Non-dual Eligible

Area level:

ZIP code level – Area Deprivation Index (ADI) from Census data (2015). Based on patient zip-code. Shen JI, Chen L, Vangala S, Leng L, Shah A, Saxena AB, Perl J, Norris KC. Socioeconomic Factors and Racial and Ethnic Differences in the Initiation of Home Dialysis Kidney Med. 2020 Feb 11;2(2):105-115. doi: 10.1016/j.xkme.2019.11.006. eCollection 2020 Mar-Apr.

Published literature:

King A, Lopez FY, Lissanu L, Robinson E, Almazan E, Metoyer G, Tanumihardjo J, Quinn M, Peek M, Saunders M. Renal Replacement Knowledge and Preferences for African Americans With Chronic Kidney Disease J Ren Care. 2020 Sep;46(3):151-160. doi: 10.1111/jorc.12312. Epub 2020 Jan 9

Mehrotra R, Soohoo M, Rivara MB, Himmelfarb J, Cheung AK, Arah OA, Nissenson AR, Ravel V, Streja E, Kuttykrishnan S, Katz R, Molnar MZ, Kalantar-Zadeh K. Racial and Ethnic Disparities in Use of and Outcomes with Home Dialysis in the United States J Am Soc Nephrol. 2016 Jul;27(7):2123-34. doi: 10.1681/ASN.2015050472. Epub 2015 Dec 10.

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Shen JI, Erickson KF, Chen L, Vangala S, Leng L, Shah A, Saxena AB, Perl J, Norris KC. Expanded Prospective Payment System and Use of and Outcomes with Home Dialysis by Race and Ethnicity in the United States Clin J Am Soc Nephrol. 2019 Aug 7;14(8):1200-1212. doi: 10.2215/CJN.00290119. Epub 2019 Jul 18.

Perez JJ, Zhao B, Qureshi S, Winkelmayer WC, Erickson KF. Health Insurance and the Use of Peritoneal Dialysis in the United States Am J Kidney Dis. 2018 Apr;71(4):479-487. doi: 10.1053/j.ajkd.2017.09.024. Epub 2017 Dec 23

Thorsness R, et al. Association of Social Risk Factors With Home Dialysis and Kidney Transplant Rates in Dialysis Facilities. JAMA December 14, 2021 326(22): pp.2323-2325.

University of Michigan Kidney Epidemiology and Cost Center. Effective Availability and Utilization of Home Dialysis Technical Expert Panel Summary Report, Prepared for The Centers for Medicare and Medicaid Services. June, 2021.

Walker DR, Inglese GW, Sloand JA, Just PM. Dialysis facility and patient characteristics associated with utilization of home dialysis Clin J Am Soc Nephrol. 2010 Sep;5(9):1649-54. doi: 10.2215/CJN.00080110. Epub 2010 Jul 15.

Category	Covariates	Hazard Ratio	95% CI	p-value
*	25 < Age <= 35	1.919	1.813, 2.032	< 0.001
*	35 < Age <= 45	1.689	1.611, 1.77	< 0.001
*	45 < Age <= 55	1.249	1.198, 1.301	< 0.001
*	55 < Age <= 65	Reference	*	*
*	65 < Age <= 75	0.83	0.8, 0.862	< 0.001
*	75 < Age <= 85	0.58	0.553, 0.61	< 0.001
*	Age > 85	0.376	0.337, 0.418	< 0.001
BMI	*	*	*	*
*	BMI < 18.5	0.875	0.801, 0.955	0.003
*	18.5 ≤ BMI < 25	Reference	*	*
*	25≤ BMI < 30	1.141	1.102, 1.182	< 0.001
*	BMI≥30	1.05	1.016, 1.086	0.005
Cause of ESRD	*	*	*	*
*	Diabetes	0.973	0.934, 1.014	0.224
*	Missing	0.473	0.151, 1.481	0.202
Incident Comorbidities	*	*	*	*
*	Atherosclerotic heart disease	1.082	1.035, 1.132	0.001
*	Malignant neoplasm, cancer	1.083	1.024, 1.143	0.004
*	Other cardiac disease	1.031	0.994, 1.071	0.106
*	Peripheral vascular disease	0.91	0.863, 0.96	< 0.001
*	Chronic obstructive pulmonary disease	0.887	0.844, 0.934	< 0.001
*	Tobacco use (current smoker)	0.886	0.838, 0.935	< 0.001
*	Congestive heart failure	0.857	0.829, 0.886	< 0.001
*	Diabetes	0.838	0.799, 0.878	< 0.001
*	Cerebrovascular disease, CVA, TIA	0.818	0.776, 0.862	< 0.001
*	Inability to transfer	0.796	0.692, 0.914	0.001
*	Alcohol dependence	0.661	0.583, 0.749	< 0.001
*	Inability to ambulate	0.484	0.44, 0.533	< 0.001
*	Drug dependence	0.367	0.312, 0.432	< 0.001
*	At least one incident comorbidity	0.882	0.844, 0.923	< 0.001
Year	*	*	*	*
*	2016	0.791	0.767, 0.817	< 0.001

Category	Covariates	Hazard Ratio	95% CI	p-value
*	2017	0.874	0.847, 0.902	< 0.001
*	2018	Reference	*	*

SMoSR Model Coefficients, Data Years 2016–2018.

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[Response Ends]

2b.25. Describe the analyses and interpretation resulting in the decision to select or not select social risk factors.

Examples may include prevalence of the factor across measured entities, availability of the data source, empirical association with the outcome, contribution of unique variation in the outcome, or assessment of between-unit effects and within-unit effects. Also describe the impact of adjusting for risk (or making no adjustment) on providers at high or low extremes of risk.

[Response Begins]

The table below shows the parameter estimates for patient-level SDS/SES variables based on a Cox model for modality switch that included these variables along with the original covariates adjusted for in SMoSR.

Table 13: Comparing coefficients between sensitivity models with and without SDS/SES adjustors, 2016-2019: SMoSR Model coefficients

*	Baseline SMoSR	*	SDS/SED-adjusted SMoSR	*
Covariates	**Hazard Ratio**	**p-value**	**Hazard Ratio**	**p-value**
Gender	*	*	*	*
Female	NA	NA	0.99	0.447
Race	*	*	*	*
White	NA	NA	Reference	
Black	NA	NA	0.592	< 0.001
Asian/Pacific Islander	NA	NA	0.858	< 0.001
Native American / Alaskan Native	NA	NA	0.667	< 0.001
other race	*	*	0.836	0.195
Ethnicity	*	*	*	*
Non-Hispanic	NA	NA	Reference	*
Hispanic	NA	NA	0.666	< 0.001
Dual Eligible Status	*	*	*	*
Non-Dual eligible	NA	NA	Reference	*

*	**Baseline SMoSR**	*	**SDS/SED-adjusted SMoSR**	*
Dual Eligible	NA	NA	0.57	< 0.001
Area Level SES Deprivation	*	*	*	*
ADI	NA	NA	0.694	< 0.001
Employment status 6 months prior to ESRD	*	*	*	*
Employed	NA	NA	1.993	< 0.001
Retired/Other/Unknown	NA	NA	1.234	< 0.001
Unemployed	NA	NA	Reference	*
Age	*	*	*	*
18 < Age <= 25	2.082	< 0.001	2.195	< 0.001
25 < Age <= 35	1.919	< 0.001	2.065	< 0.001
35 < Age <= 45	1.689	< 0.001	1.761	< 0.001
45 < Age <= 55	1.249	< 0.001	1.265	< 0.001
55 < Age <= 65	Reference		Reference	
65 < Age <= 75	0.83	< 0.001	0.825	< 0.001
75 < Age <= 85	0.58	< 0.001	0.57	< 0.001
Age > 85	0.376	< 0.001	0.367	< 0.001
Body Mass Index	*	*	*	*
BMI < 18.5	0.875	0.003	0.911	0.041
18.5 ≤ BMI < 25	Reference	*	Reference	*
25≤ BMI < 30	1.141	< 0.001	1.111	< 0.001
BMI≥30	1.05	0.005	1.015	0.403
Cause of ESRD	*	*	*	*
Diabetes	0.973	0.224	0.991	0.677
Missing	0.473	0.202	0.53	0.274
Incident Comorbidities	*	*	*	*
Atherosclerotic heart disease	1.082	0.001	1.048	0.043
Malignant neoplasm, cancer	1.083	0.004	1.02	0.474
Other cardiac disease	1.031	0.106	1	0.992
Peripheral vascular disease	0.91	< 0.001	0.908	< 0.001
Chronic obstructive pulmonary disease	0.887	< 0.001	0.902	< 0.001
Tobacco use (current smoker)	0.886	< 0.001	0.914	0.001

*	**Baseline SMoSR**	*	**SDS/SED-adjusted SMoSR**	*
At least one incident comorbidity	0.882	< 0.001	0.919	< 0.001
Congestive heart failure	0.857	< 0.001	0.887	< 0.001
Diabetes	0.838	< 0.001	0.877	< 0.001
Cerebrovascular disease, CVA, TIA	0.818	< 0.001	0.868	< 0.001
Inability to transfer	0.796	0.001	0.826	0.007
Alcohol dependence	0.661	< 0.001	0.674	< 0.001
Inability to ambulate	0.484	< 0.001	0.516	< 0.001
Drug dependence	0.367	< 0.001	0.433	< 0.001
Year	*	*	*	*
2016	0.791	< 0.001	0.797	< 0.001
2017	0.874	< 0.001	0.879	< 0.001
2018	Reference	*	Reference	*

Comparing coefficients between sensitivity models with and without SDS/SES adjustors, 2016-2019: SMoSR Model coefficients

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Figure 3: Comparison of SMoSR Model with and without SES/SDS

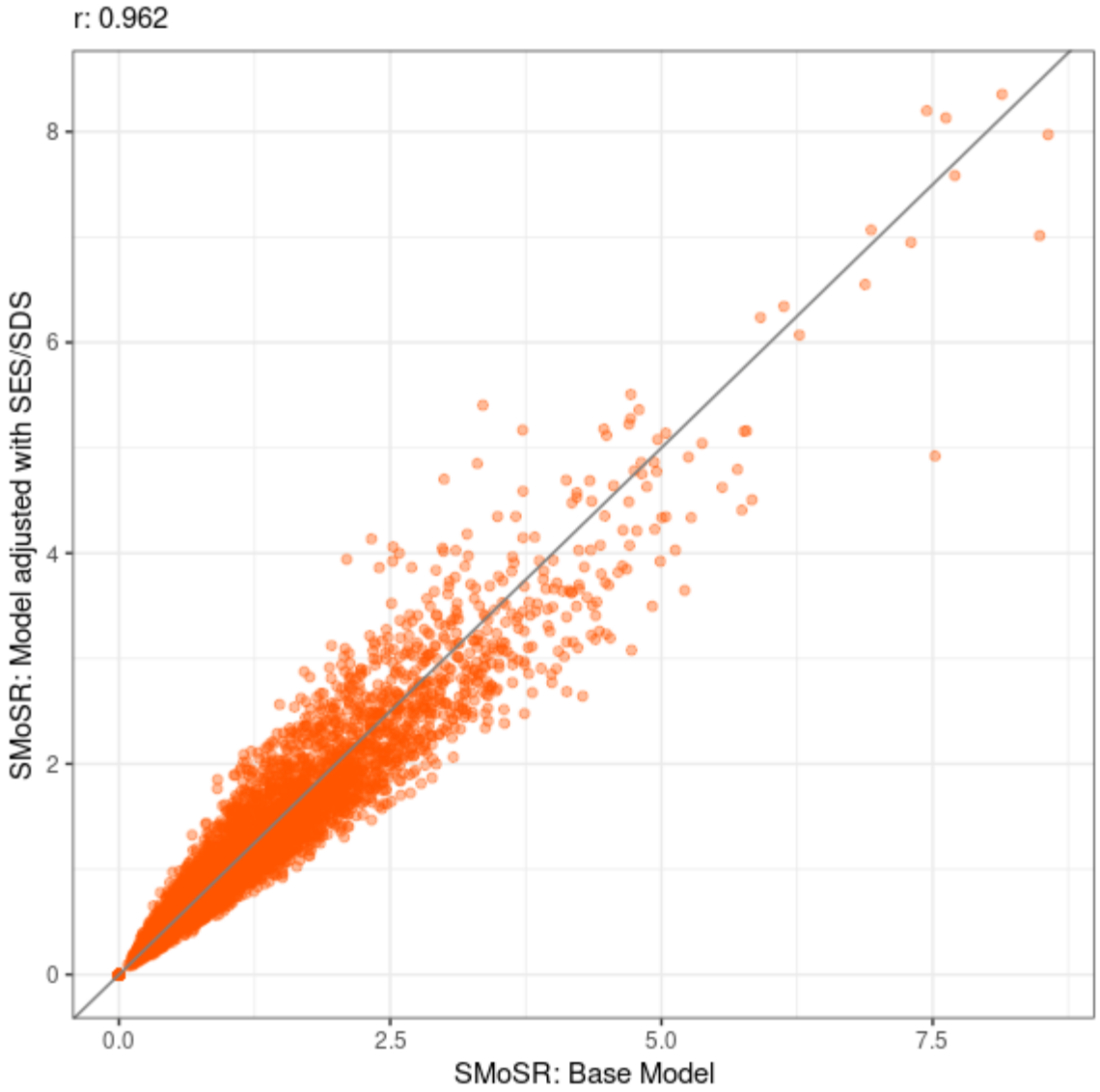


Table 14: Comparison of SMoSR Model with and without SES/SDS

*	**SMoSR Without SES/SDS (current model)**	*	*	*
Facility Performance	Better than expected	As expected	Worse than expected	**Total**
SMoSR With SES/SDS	*	*	*	*
Better than expected	374 (6.3%)	62 (1.0%)	0 (0%)	436 (7.4%)
As expected	87 (1.5%)	5,090 (86%)	87 (1.5%)	5,264 (89%)
Worse than expected	0 (0%)	51 (0.9%)	174 (2.9%)	225 (3.8%)
Total	461 (7.8%)	5,203 (88%)	261 (4.4%)	5,925 (100%)

Comparison of SMoSR Model with and without SES/SDS

*cells left intentionally blank

(Pearson's r=0.962).

Table 13 reports results of the SMoSR model that includes adjustment for social risk factors of race, ethnicity, sex, dual eligible status, employment status, and area deprivation. Black patients, Asian/Pacific Islander, Native American/Alaskan Native patients had a 40%, 15%, and 33%, respectively, lower hazard of switching from in-center dialysis to a home modality in their first year of dialysis (all p<0.001). Patients of Hispanic ethnicity also had a 34% lower hazard (p<0.001) of switching modality from in-center to home dialysis, while the impact on females was no different than males. These findings are consistent with the published literature (e.g., Shen 2020; Mehrotra 2015). Among SES factors, employment status at incidence, dual eligible status and area level SES deprivation (ADI) were associated with modality switch events. Employment at ESRD incidence was associated with 99% higher hazard (p<0.001) of switching from in-center to home dialysis treatment while patients with Medicare dual eligible status or in areas with higher SES deprivation had lower hazard of modality switch (43%, 31%, respectively, all p<0.001). This is consistent with the literature (e.g., Perez 2018; Thorsness 2021) that suggest people with lower SES have lower uptake of a home dialysis modality. The lower uptake is potentially based on an assumption that patients with lower SESE do not have the material and social resources needed to support dialysis at home. Similarly, facilities may generally not encourage home dialysis for patients that they feel may not be able to successfully do dialysis at home due to limited social and economic resources.

Table 14 and figure 3 show results that compare facility performance between the base model that does not adjust for social risk factors, to a model that includes adjustment for race, ethnicity, sex, dual eligible status, employment status at ESRD incidence, and area deprivation. After adjustment for these social risk factors, 287 facilities (4.8%) changed performance categories. One-hundred thirty-eight (2.3%) facilities moved to a lower performance category, and 149 (2.5 %) moved to a higher performance category. SMoSR with and without adjustment for patient SDS/SES were highly correlated (Pearson's r=0.962).

There are known disparities in uptake of home dialysis modalities among people of Black race, Hispanic ethnicity, and lower socioeconomic status. This was further highlighted in a recent study examining the association of social risk factors and uptake of home dialysis (Thorsness et al 2021). Overall the study reported that facilities with higher percentages of patients with social risk factors of race, ethnicity, or Medicaid coverage were less likely to offer peritoneal dialysis and had lower rates of initiation of home dialysis. These findings are generally consistent with other peer-reviewed literature that has reported lower uptake of home dialysis in these populations (e.g., Shen 2020; Mehrotra 2015). Thorsness et al (2021) suggested consideration of risk adjustment to assure a fair assessment of facilities with higher proportions of patients with social risk factors. However, there was no examination whether the source of these differences was related to disparities in care and access to home modalities, in which case adjustment would not be appropriate.

Race, Hispanic ethnicity, female sex, and SES factors are not included in the final risk adjusted model for SMoSR. While these factors are associated with decreased uptake of home dialysis in patient-level analyses, the impact is largely attenuated at the facility-level analysis of flagging. That is, 95.2% of facilities performance category will not change with or without adjustment for these social risk factors. Furthermore, among the 4.8% of facilities whose performance category does change with SES/SDS adjustment, the 2.5% of facilities who move to a higher performance category are offset by the 2.3% of facilities that move to a lower performance category. Further work is needed to demonstrate that differences based on these factors are not related to facility processes of care and differences in the education provided to patients about home dialysis, in order to prevent disparities in care. While there is a push to include social risk factors as adjustments in performance measures, this has potential unintended consequences that may exacerbate disparities. In the absence of definitive evidence demonstrating risk adjustment for these social factors does not result in differential access to care, the most appropriate decision is not to risk adjust for these SDS/SES factors. The primary goal should be to implement quality measures that result in the highest quality of patient care and equitable access for all patients to that care.

Finally, the 2021 Technical Expert Panel consensus was there are known disparities between social risk factors and uptake of home dialysis. TEP members expressed concern that adjusting for social risk factors of race,

ethnicity, sex, and SES could potentially further disadvantage patients based on their race, ethnicity, or lack of SES-based resources (UM-KECC, 2021). During the TEP, CMS noted potential legal challenges with implementing race and ethnicity adjustment factors in Federal Payment programs.

[Response Ends]

2b.26. Describe the method of testing/analysis used to develop and validate the adequacy of the statistical model or stratification approach (describe the steps—do not just name a method; what statistical analysis was used). Provide the statistical results from testing the approach to control for differences in patient characteristics (i.e., case mix) below. If stratified ONLY, enter "N/A" for questions about the statistical risk model discrimination and calibration statistics.

Validation testing should be conducted in a data set that is separate from the one used to develop the model.

[Response Begins]

Risk factors were selected for the final model based on the magnitude of the coefficients, evaluation of their statistical significance, and the model C-statistic. The C-statistic measures the discriminative power of the regression model with considered risk factors.

[Response Ends]

2b.27. Provide risk model discrimination statistics.

For example, provide c-statistics or R-squared values.

[Response Begins]

In this model, the C-Statistic=0. 674, which suggests good predictive ability of the risk model.

[Response Ends]

2b.28. Provide the statistical risk model calibration statistics (e.g., Hosmer-Lemeshow statistic).

[Response Begins]

N/A

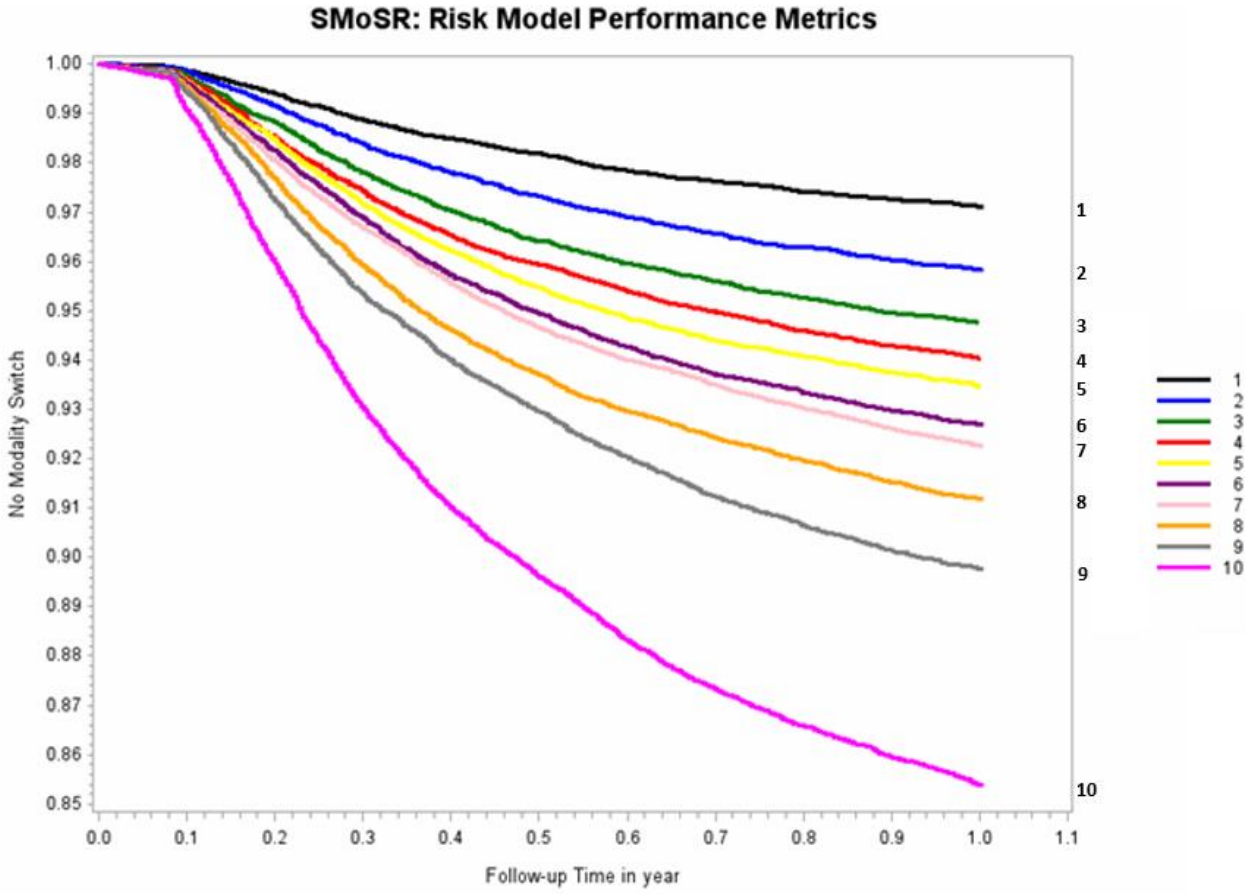
[Response Ends]

2b.29. Provide the risk decile plots or calibration curves used in calibrating the statistical risk model.

The preferred file format is .png, but most image formats are acceptable.

[Response Begins]

Figure 4. Decile plot for SMoSR



[Response Ends]

2b.30. Provide the results of the risk stratification analysis.

[Response Begins]

N/A

[Response Ends]

2b.31. Provide your interpretation of the results, in terms of demonstrating adequacy of controlling for differences in patient characteristics (i.e., case mix).

In other words, what do the results mean and what are the norms for the test conducted?

[Response Begins]

Figure 4 is the decile plot showing estimates of cumulative rates with no modality switch by follow-up time. The plot shows that the risk factors in the model are discriminating well between patients. There is good separation among all 10 groups and the ordering is as predicted by the model (patients predicted to be at higher risk of not switching to home dialysis have the lowest modality switch rates). The absolute differences between the groups is also large at one year ranging from 98% for those patients predicted to have the lowest modality switch rates (group 1) down to 85% for those predicted to have the highest rates of modality switch (group 10).

[Response Ends]

2b.32. Describe any additional testing conducted to justify the risk adjustment approach used in specifying the measure.

Not required but would provide additional support of adequacy of the risk model, e.g., testing of risk model in another data set; sensitivity analysis for missing data; other methods that were assessed.

[Response Begins]

N/A

[Response Ends]

Criterion 3. Feasibility

Extent to which the specifications including measure logic, require data that are readily available or could be captured without undue burden and can be implemented for performance measurement.

3.01. Check all methods below that are used to generate the data elements needed to compute the measure score.

[Response Begins]

Generated or collected by and used by healthcare personnel during the provision of care (e.g., blood pressure, lab value, diagnosis, depression score)

Coded by someone other than person obtaining original information (e.g., DRG, ICD-10 codes on claims)

[Response Ends]

3.02. Detail to what extent the specified data elements are available electronically in defined fields.

In other words, indicate whether data elements that are needed to compute the performance measure score are in defined, computer-readable fields.

[Response Begins]

ALL data elements are in defined fields in a combination of electronic sources

[Response Ends]

3.03. If ALL the data elements needed to compute the performance measure score are not from electronic sources, specify a credible, near-term path to electronic capture, OR provide a rationale for using data elements not from electronic sources.

[Response Begins]

N/A

[Response Ends]

3.04. Describe any efforts to develop an eCQM.

[Response Begins]

N/A

[Response Ends]

3.06. Describe difficulties (as a result of testing and/or operational use of the measure) regarding data collection, availability of data, missing data, timing and frequency of data collection, sampling, patient confidentiality, time and cost of data collection, other feasibility/implementation issues.

[Response Begins]

None identified.

[Response Ends]

Consider implications for both individuals providing data (patients, service recipients, respondents) and those whose performance is being measured.

3.07. Detail any fees, licensing, or other requirements to use any aspect of the measure as specified (e.g., value/code set, risk model, programming code, algorithm),

Attach the fee schedule here, if applicable.

[Response Begins]

N/A

[Response Ends]

Criterion 4: Use and Usability

4a. Use

Extent to which potential audiences (e.g., consumers, purchasers, providers, policy makers) are using or could use performance results for both accountability and performance improvement to achieve the goal of high-quality, efficient healthcare for individuals or populations.

Extent to which intended audiences (e.g., consumers, purchasers, providers, policy makers) can understand the results of the measure and are likely to find them useful for decision making.

NQF-endorsed measures are expected to be used in at least one accountability application within 3 years and publicly reported within 6 years of initial endorsement, in addition to demonstrating performance improvement.

4a.01. Check all current uses. For each current use checked, please provide:

Name of program and sponsor

URL

Purpose

Geographic area and number and percentage of accountable entities and patients included

Level of measurement and setting

[Response Begins]

Not in use

[Not in use Please Explain]

The measure is undergoing initial endorsement review.

[Response Ends]

4a.02. Check all planned uses.

[Response Begins]

Public reporting

Payment Program

[Response Ends]

4a.03. If not currently publicly reported OR used in at least one other accountability application (e.g., payment program, certification, licensing), explain why the measure is not in use.

For example, do policies or actions of the developer/steward or accountable entities restrict access to performance results or block implementation?

[Response Begins]

The measure is undergoing initial endorsement review.

[Response Ends]

4a.04. If not currently publicly reported OR used in at least one other accountability application, provide a credible plan for implementation within the expected timeframes: used in any accountability application within 3 years, and publicly reported within 6 years of initial endorsement.

A credible plan includes the specific program, purpose, intended audience, and timeline for implementing the measure within the specified timeframes. A plan for accountability applications addresses mechanisms for data aggregation and reporting.

[Response Begins]

CMS will determine if/when to report this measure in a public reporting/payment program. Potential applications for the measure include the ESRD Quality Incentive Program (ESRD QIP) or the Dialysis Facility Care Compare website.

[Response Ends]

4a.05. Describe how performance results, data, and assistance with interpretation have been provided to those being measured or other users during development or implementation.

Detail how many and which types of measured entities and/or others were included. If only a sample of measured entities were included, describe the full population and how the sample was selected.

[Response Begins]

Facility level results have not been disseminated to those being measured as part of the development process. The measure developer sought input from a technical expert panel in 2021, during development, and those deliberations were open to the public. The TEP summary report was also posted publicly on the CMS website (and is now posted <link to dialysisdata.org>). The TEP was comprised of stakeholders representing dialysis facility providers and ESRD and dialysis patients.

[Response Ends]

4a.06. Describe the process for providing measure results, including when/how often results were provided, what data were provided, what educational/explanatory efforts were made, etc.

[Response Begins]

Initial measure results from development testing were reviewed by the TEP, however facility level results have not been disseminated to those being measured as part of the development process. Feedback from the TEP is summarized in the TEP summary report.

[Response Ends]

4a.07. Summarize the feedback on measure performance and implementation from the measured entities and others. Describe how feedback was obtained.

[Response Begins]

N/A, since the measure is not yet implemented, and results have not been disseminated.

[Response Ends]

4a.08. Summarize the feedback obtained from those being measured.

[Response Begins]

As described above, the developer sought input from a technical expert panel during the development of this measure. This group was comprised of stakeholders from dialysis facilities (those being measured) as well as other stakeholders including a significant number of ESRD patients on dialysis or who had been on dialysis.

In summary, there was broad consensus from the TEP that home dialysis is underutilized and that a quality measure to monitor facility performance would be useful to patients, providers, and other stakeholders.

The TEP supported the basic construct of the Standardized Modality Switch Ratio (SMoSR) Measure. The TEP further also agreed the proposed measure should be considered for modification over time, taking into account new information subsequent to future implementation.

[Response Ends]

4a.09. Summarize the feedback obtained from other users.

[Response Begins]

See 4a.08

[Response Ends]

4a.10. Describe how the feedback described has been considered when developing or revising the measure specifications or implementation, including whether the measure was modified and why or why not.

[Response Begins]

As part of the TEP process, the developer presented a draft version of SMoSR for discussion. Several changes were made to the measure specifications based on input from the TEP, such as the definition of a durable switch. Further details can be found in the TEP report.

[Response Ends]

4b. Usability

4b.01. You may refer to data provided in Importance to Measure and Report: Gap in Care/Disparities, but do not repeat here. Discuss any progress on improvement (trends in performance results, number and percentage of people receiving high-quality healthcare; Geographic area and number and percentage of accountable entities and patients included). If no improvement was demonstrated, provide an explanation. If not in use for performance improvement at the time of initial endorsement, provide a credible rationale that describes how the performance results could be used to further the goal of high-quality, efficient healthcare for individuals or populations.

[Response Begins]

The measure is not yet implemented in a public reporting program, so improvement could not be evaluated. CMS currently anticipates implementation of this measure. Once implemented, facility performance on the measure can be evaluated to determine if the measure has supported and detected quality improvement in home dialysis rates among the target population.

[Response Ends]

4b.02. Explain any unexpected findings (positive or negative) during implementation of this measure, including unintended impacts on patients.

[Response Begins]

None, as the measure is not yet implemented

[Response Ends]

4b.03. Explain any unexpected benefits realized from implementation of this measure.

[Response Begins]

None, as the measure is not yet implemented

[Response Ends]

Criterion 5: Related and Competing Measures

If a measure meets the above criteria and there are endorsed or new related measures (either the same measure focus or the same target population) or competing measures (both the same measure focus and the

same target population), the measures are compared to address harmonization and/or selection of the best measure.

If you are updating a maintenance measure submission for the first time in MIMS, please note that the previous related and competing data appearing in question 5.03 may need to be entered in to 5.01 and 5.02, if the measures are NQF endorsed. Please review and update questions 5.01, 5.02, and 5.03 accordingly.

5.01. Search and select all NQF-endorsed related measures (conceptually, either same measure focus or target population).

(Can search and select measures.)

[Response Begins]

[Response Ends]

5.02. Search and select all NQF-endorsed competing measures (conceptually, the measures have both the same measure focus or target population).

(Can search and select measures.)

[Response Begins]

[Response Ends]

5.03. If there are related or competing measures to this measure, but they are not NQF-endorsed, please indicate the measure title and steward.

[Response Begins]

N/A

[Response Ends]

5.04. If this measure conceptually addresses EITHER the same measure focus OR the same target population as NQF-endorsed measure(s), indicate whether the measure specifications are harmonized to the extent possible.

[Response Begins]

[Response Ends]

5.05. If the measure specifications are not completely harmonized, identify the differences, rationale, and impact on interpretability and data collection burden.

[Response Begins]

N/A

[Response Ends]

5.06. Describe why this measure is superior to competing measures (e.g., a more valid or efficient way to measure quality). Alternatively, justify endorsing an additional measure.

Provide analyses when possible.

[Response Begins]

N/A

[Response Ends]

Appendix

Supplemental materials may be provided in an appendix.: Available in attached file

Contact Information

Measure Steward (Intellectual Property Owner): Centers for Medicare & Medicaid Services

Measure Steward Point of Contact: Dollar-Maples, Helen, helen.dollar-maples@cms.hhs.gov

Measure Developer if different from Measure Steward: University of Michigan Kidney Epidemiology and Cost Center

Measure Developer Point(s) of Contact: George, Jaclyn, jaclynrg@med.umich.edu

Yaldo, Alexander, yaldo@med.umich.edu

Sardone, Jennifer, jmsto@med.umich.edu

Parrotte, Casey, parrotte@umich.edu

Additional Information

1. Provide any supplemental materials, if needed, as an appendix. All supplemental materials (such as data collection instrument or methodology reports) should be collated one file with a table of contents or bookmarks. If material pertains to a specific criterion, that should be indicated.

[Response Begins]

Available in attached file

[Response Ends]

2. List the workgroup/panel members' names and organizations.

Describe the members' role in measure development.

[Response Begins]

Derek Forfang *(TEP Co-Chair),* Patient Advocate

Brigitte Schiller MD *(TEP Co-Chair*), Nephrologist, Chief Medical Officer, Satellite Healthcare

Rodney Carter, Patient Advocate

Michelle Cassin RN, CPDN, DaVita Kidney Care

Glenn Chertow MD, MPH, Nephrologist, Professor of Medicine and Professor of Epidemiology and Population Health, Stanford University School of Medicine

Paul T. Conway BA, Chair of Policy and Global Affairs- American Association of Kidney Patients

Richard Knight MBA, President, American Association of Kidney Patients

April McGraw BSN, RN, CNN, Patient Advocate and Dialysis Nurse, DaVita Kidney Care

Rajnish Mehortra MD, Nephrologist, University of Washington

Matthew Oliver MD, MHS, FRCPC, Nephrologist, University of Toronto; Sunnybrook Health Sciences Centre; ISPD- North American Chapter

Amber Pettis, BS, Biochemistry; MBA, Patient Advocate, National Kidney Foundation

Cheri Rodriques Jones, Patient Advocate

Martin Schreiber MD, Nephrologist, Chief Medical Officer Home Modalities, DaVita Kidney Care

Stacy Cigliana RN, CNN, VP Clinical Services- Home Therapies, US Renal Care

Isaac Teitelbaum MD, Nephrologist, University of Colorado, Anschutz Medical Center

Eric Weinhandl PhD, Epidemiologist, Chronic Disease Research Group

[Response Ends]

3. Indicate the year the measure was first released.

[Response Begins]
2022
[Response Ends]

4. Indicate the month and year of the most recent revision.

[Response Begins]
1/2022
[Response Ends]

5. Indicate the frequency of review, or an update schedule, for this measure.

[Response Begins]
Annually
[Response Ends]

6. Indicate the next scheduled update or review of this measure.

[Response Begins]
Initial Review scheduled for 04/2022
[Response Ends]

7. Provide a copyright statement, if applicable. Otherwise, indicate "N/A".

[Response Begins]
N/A
[Response Ends]

8. State any disclaimers, if applicable. Otherwise, indicate "N/A".

[Response Begins]

N/A

[Response Ends]

9. Provide any additional information or comments, if applicable. Otherwise, indicate "N/A".

[Response Begins]

N/A

[Response Ends]