Dialysis Facility Quality of Patient Care Star Ratings Technical Expert Panel Summary Report

March 2022

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Overview

The Centers for Medicare & Medicaid Services (CMS) has contracted with the University of Michigan Kidney Epidemiology and Cost Center (UM-KECC) to act as the quality measure developer and technical content support contractor for Care Compare on Medicare.gov, under the Kidney Disease Quality Measure Development, Maintenance, and Support contract (contract #75FCMC18D0041, task order #75FCMC18F0001). As part of this contract, UM-KECC convenes technical expert panels (TEPs) to obtain consumer and provider input for quality measure development and the Medicare.gov Dialysis Facility Quality of Patient Care Star Rating (Star Rating). UM-KECC sought nominations from individuals with relevant clinical and methodological experience and perspectives, including ESRD patients with dialysis experience to serve on this 2022 TEP.

A Star Rating TEP was first convened in 2015 to review the original methodology and presentation of the Star Rating on the Medicare.gov website. The TEP provided several recommendations that were implemented in the updated Star Rating methodology, released in October 2016. A second TEP was convened in 2017. TEP members provided recommendations on candidate measures proposed for inclusion in the Star Rating and defined concepts such as rebaselining and resetting. A third TEP was convened in 2019 to provide recommendations on options for resetting the Star Rating and reweighting one of the quality domains in the calculation of the Star Rating. See the respective 2015, 2017, and 2019 Star Rating TEP summary reports for the deliberations and TEP recommendations, available at:

https://dialysisdata.org/content/esrd-measures

As part of CMS' broader initiative for Care Compare on Medicare.gov (www.medicare.gov/care-compare/), CMS developed the Star Rating to make quality information more accessible to patients, caregivers, providers, and policymakers and to help consumers (including patients and caregivers) understand CMS quality measures and more easily identify differences in overall quality when selecting dialysis facilities. The Medicare.gov website displays two star ratings: (1) the Quality of Patient Care Star Rating and (2) the Survey of Patients' Experiences Star Rating. Eleven of the quality measures currently reported on the Medicare.gov website are used to calculate the Quality of Patient Care Star Rating. The Survey of Patients' Experiences Star Ratings was not covered as a discussion topic during this TEP. Broadly, this TEP was expected to review and provide input on options and considerations for updating and public reporting of the Star Rating.

Technical Expert Panel Charter: TEP Objectives

UM-KECC, through its contract with CMS, convened a TEP to obtain recommendations related to the first public release of the Quality of Patient Care Star Rating (hereafter, "Star Rating") since the start of the COVID-19 pandemic, a public health emergency, in spring 2020. The 2022 Star Rating TEP was expected to focus on:

1. Providing recommendations on the addition of two measures related to transplant waitlisting
2. Establishment of a new baseline against which to score facility performance related to considerations of the impact of COVID-19 on data reporting and ESRD dialysis outcomes
3. Discussing the potential public reporting of a continuous Star Rating score on Medicare.gov (this topic was not discussed during the TEP meetings)

It is intended that the final methodology developed ensures the Star Rating continues to be informative by reflecting meaningful performance differences among facilities.

Technical Expert Panel Composition

A public call for nominations opened on Wednesday, December 8, 2021 and closed on Friday, January 14, 2022. Nominations were sought from individuals with the following areas of expertise or experiential perspectives:

- Individuals with end-stage renal disease (ESRD) and caregivers of individuals with ESRD
- Individuals with subject matter expertise, e.g., scientists in nephrology care; clinicians and nurses; consumer testing experts; experts in consumer communication
- Individuals with methodological expertise, e.g., statisticians/biostatisticians with expertise in score or scale development, multivariate analysis, risk assessment, latent variable modeling
- Individuals with dialysis facility quality improvement expertise
- Individuals with health care disparities expertise

The following individuals listed in Table 1 were selected to serve on the TEP:

Table 1: Technical Expert Panel Composition and Contractor Staff

Name and Credentials	Organizational Affiliation, City, State	Conflicts of Interest Disclosed
Paul T. Conway *(TEP Co-Chair)* Patient Advocate, Chair, Policy and Global Affairs	American Association of Kidney Patients Tampa, FL	None Reported
Nicole Stankus, MD, MSc *(TEP Co-Chair)* Nephrologist	University of Chicago, IL	None Reported
Andrew Conkling Patient Advocate	Washington, DC	None Reported
Mary Dittrich, MD, FASN Nephrologist, Chief Medical Officer	US Renal Care Boise, ID	Shareholder and CMO of US Renal Care and owns share in multiple dialysis units
Stephanie Dixon Patient Advocate	National Forum of ESRD Networks Brooklyn, NY	None Reported
Nupar Gupta, MD Nephrologist, Assistant Professor of Clinical Medicine	Indiana University School of Medicine Indianapolis, IN	None Reported
Emel Hamilton, MD MSN/INF, CNN Vice President of Clinical Support and Clinical Informatics/ non practicing physician, RN license	Fresenius Medical Care Waltham, MA	Employee of Fresenius Kidney Care
Syed Ali Husain, MD, MPH, MA, FASN Nephrologist	Columbia University Medical Center New York, NY	None Reported
Richard Knight, MBA Patient Advocate	American Association of Kidney Patients Tampa, FL	None Reported
Mahesh Krishnan, MD, MPH, MBA, FASN Group Vice President of Research and Development	DaVita Washington, DC	Employed at DaVita and owns stock
Diane Morris, MS, RN, CNN Director of Nursing and Clinical Services	The Rogosin Institute New York, NY	None Reported

Name and Credentials	Organizational Affiliation, City, State	Conflicts of Interest Disclosed
Curtis Warfield, MS Patient Advocate	National Kidney Foundation Home Dialyzors United, Indianapolis, IN	None Reported
Eric Weinhandl, PhD, MS Epidemiology Senior Director, Data Analytics and Home Therapies	Satellite Healthcare Victoria, MN	Employee of a Dialysis provider
Contractor Staff		
Yi Li, PhD	*Professor, Biostatistics* *Professor, Global Public Health*	None
Joseph Messana, MD	*Professor, Internal Medicine, Division of Nephrology* *Research Professor, Health Management and Policy*	None
Claudia Dahlerus, PhD	*Assistant Research Scientist, Internal Medicine* *Division of Nephrology*	None
Richard Hirth, PhD	*S.J. Axelrod Collegiate Professor, Health Management and Policy Professor, Internal Medicine*	None
Peisong Han, PhD	*Associate Professor, Biostatistics*	None
Garrett Gremel, MS	*Senior Analyst*	None
Tao Xu, PhD	*Senior Analyst*	None
Casey Parrotte, BA, PMP	*Continued Improvement Specialist Lead*	None
Jennifer Sardone, BA, PMP	*Lead Project Manager*	None
Eileen Yang, BS	*PhD Student, Biostatistics*	None
Stephen Salerno, MS	*PhD Student, Biostatistics*	None
Jaclyn George	*Project Intermediate Manager*	None

1. Introduction

This report summarizes the discussions and recommendations of the Dialysis Facility Star Rating TEP meetings convened on February 17, 2022, and March 3, 2022. All meetings were public and held virtually via Zoom video-conference. The TEP provided advice and expert input on two specific questions. First, the TEP discussed whether either or both transplant waitlisting measures currently reported on the Care Compare site for dialysis facilities should be included in the Star Rating. Second, the TEP provided opinions and justifications for choice of a new baseline period for calculation of the updated Star Rating when CMS decides when to implement the update.

2. Preliminary Activities

2.1 TEP Charter

The Dialysis Facility Star Rating TEP Charter (Appendix A) was distributed to the TEP members for review prior to the first meeting. At the first meeting, key elements of the charter were highlighted, focusing on the process for developing and updating the Star Rating methodology. In particular, the role of the TEP was outlined, and the following responsibilities were highlighted:

- Review empirical data and analytic results to determine the basis of support for the proposed update(s) related to topics identified in the TEP charter
- Review and approve the summary report of the TEP meeting and provide input on other necessary technical documentation required for public reporting or for response to public comments
- Be available for follow up conference calls, as needed
- TEPs are advisory to the contractor (UM-KECC), and not CMS.
  It is the responsibility of UM-KECC to accurately report and consider recommendations received from the TEP; however, recommendations made to CMS are made by UM-KECC, and not by the TEP
- If UM-KECC makes recommendations to CMS that are not consistent with consensus recommendations from the TEP, it is UM-KECC's responsibility to explain the rationale for any differences

No objections were raised regarding the TEP charter.

3. Overview of the Dialysis Facility Star Rating Methodology

An overview of the Star Rating system was presented to the TEP. The Star Rating is intended to be an easy-to-interpret summary of the quality of care provided by dialysis facilities, and to give patients,

families and caregivers information to easily compare dialysis facilities. Since the Star Rating was first released in January of 2015, UM-KECC has facilitated three prior TEPs to seek recommendations on updates to the Star Rating methodology. The TEP was presented with general definitions of terms frequently used in discussion of the Star Rating:

- Measure Value: The original value of a facility's clinical quality measure, as reported on Care Compare, which represents a ratio or a percentage
- Measure Score: Values obtained by standardizing the original measure values for each measure, so that no measure has undue influence on the Star Rating and so that the range and direction of standardized values are consistent (with mean 0, variance 1)
- Domain Score: A score which summarizes a facility's performance on a group of correlated clinical quality measures. It is an average of the individual measure scores in that group (domain)
- Final Score: A continuous score calculated for each facility, which summarizes its performance on the reported clinical quality measures. It is an average of the domain scores
- Cutoff: A value of the final score that defines the boundary between two adjacent Star Rating categories (e.g., the cutoff between 4- and 5-stars is 1.36 and facilities with a final score > 1.36 receive 5 stars)

The TEP members were provided with a brief overview of how the Star Rating is calculated:

1. Measure values on different scales are standardized against the baseline period to form measure scores with the same interpretation
2. Individual measures are grouped into different measure domains based on statistical factor analysis
3. Measure scores within a domain are averaged to form domain scores
4. Domain scores are averaged to form a final score for each facility
5. Final scores are grouped into five star categories based on pre-established Star Rating cutoff values

Subsequently, the distinction between and justifications for rebaselining (establishing new scoring cut-offs for a new baseline period) and resetting (establish new baseline period, scoring cut-offs ***and*** star rating distribution) were reviewed in the context of prior Star Rating TEP decisions.

3.2 Current Star Rating Measures

TEP members were provided summary information about the current Star Rating measures. Within Domain 1 are 4 measures: Standardized Transfusion Ratio for Dialysis Facilities (STrR), Standardized Mortality Ratio for Dialysis Facilities (SMR), Standardized Hospitalization Ratio for Dialysis Facilities (SHR), and Standardized Readmission Ratio for Dialysis Facilities (SRR). Domain 2 has two measures: Hemodialysis Vascular Access: Standardized Fistula Rate (SFR), and Hemodialysis Vascular Access: Long-Term Catheter Rate (LTC). Finally, within Domain 3, there are 2 measures: Total KT/V (KT/V), and Proportion of Patients with Hypercalcemia (Hyp.)

4. Adding Transplant Waitlisting Measures to the Star Rating

TEP members were provided with a high-level summary of kidney transplantation and the sequential processes involved in kidney transplant referral, evaluation, and waitlisting for deceased donor kidney transplantation in the United States. The two kidney transplant waitlisting measures currently reported on Dialysis Facility Care Compare were presented as contextual background for the TEP discussion.

Standardized First Kidney Transplant Waitlist Ratio (SWR) for Incident Dialysis Patients:

The SWR is defined as the observed number of patients on the transplant waitlist or who received transplants within the first year of dialysis, divided the expected number of waitlisting or transplants within the first year of dialysis, adjusted for age and incident comorbidities. For this measure, a higher value means better quality performance.

Percentage of Prevalent Patients Waitlisted (PPPW):

The PPPW is defined as the proportion of patient-months at each dialysis facility that patients were on the transplant waitlist. The numerator is number of patient-months at the dialysis facility and on the waitlist, and the denominator is all patient-months assigned to a dialysis facility for the full month. For this measure, a higher value also means better quality performance.

4.1 Adding PPPW/SWR to Star Ratings - Technical Considerations

Currently, seven measures are included in the Star Rating, grouped into three domains. When new measures are added to the Star Rating, the measure domains must be reassessed. New measures either must be added to existing domains or form new domain(s) based on an assessment of the correlation among the candidate and existing measures using a statistical technique known as *factor analysis*. Historical data from the October 2020 Star Rating release was used to estimate what would happen if either or both the SWR and PPPW were added to the Star Rating.

UM-KECC provided the TEP with an overview of considerations for potential inclusion of the two measures in the Star Rating. Grouping of measures into domains using factor analysis is to avoid a single measure or a group of correlated measures dominating the Star Rating. In the current Star Rating, patient care measures are grouped into three domains based on factor loadings: STrR, SHR, SMR, and SRR (four standardized measures) comprise Domain 1, SRR and SFR comprise Domain 2, and Kt/V and hypercalcemia measures comprise Domain 3. Within each domain, measures tend to be more correlated with each other than with those in other domains.

The preliminary analyses using historical data suggest that SWR and PPPW form a separate domain when including both of them in the Star Rating; when considering addition of only one of them to the Rating, that single measure forms a standalone domain as well. These results suggest the transplant waitlisting measures may provide additional quality information on an important aspect of care, i.e.

access to transplant, which is distinct from the aspects of care measured by the other Star Rating domains.

TEP members were also provided information on how the addition may impact individual facility ratings. In particular, the presentation showed how the rating for a facility would change if the two transplant waitlisting measures were added to Star Rating as Domain 4. As presented in Table 2, the analysis results compare the agreement of the Star Rating categories under a calculation with the current three domains (rows) versus a calculation with the transplant waitlisting measures added to the Star Rating as a fourth domain (columns). The bolded diagonal elements represent those Star categorizations which agree under both calculations (e.g., a 1-star rating under both the original domains and four domains with the transplant waitlisting measures). The off-diagonals represent those ratings which disagree between the two calculations (e.g., a 2-star rating under the original domains but a 3-star rating under four domains with the transplant waitlisting measures).

Table 2: Star Rating Agreement with Reset Baseline: Current Domains versus Four Domains with the Transplant Waitlisting Measures; Cell Values Represent Facility Percentages

3 Current Domains	4 Domains, with Transplant Waitlist Measures				
	1-Star	2-Stars	3-Stars	4-Stars	5-Stars
1-Star	**7.4%**	2.1%	0.3%	0.1%	-
2-Stars	2.5%	**12.2%**	5.0%	0.2%	-
3-Stars	-	5.6%	**27.2%**	6.0%	1.1%
4-Stars	-	0.1%	7.2%	**9.6%**	3.2%
5-Stars	-	-	0.2%	4.1%	**5.7%**

Subsequent to the presentation several TEP members had questions about the analysis results. One TEP member asked whether this table shows that 6% of facilities moved from a 3-star rating to a 4-star rating with the addition of the waitlisting measures. UM-KECC confirmed this was correct and noted that some facilities would receive a Star Rating increase with the addition of these measures. A TEP member asked, of the 35% of facilities that changed Star Rating, what percentage went up and what percentage went down. UM-KECC responded that roughly half increased and the other half decreased, because in this analysis the star rating distribution was fixed at 10% 5-stars, 20% 4-stars, 40% 3-stars, 20% 2-stars, and 10% 1-star for both scenarios, corresponding to the reset distribution. UM-KECC explained that the next step in addressing that question would be to study whether and how the change may be associated with facility characteristics.

4.2 Discussion

The co-chairs began the discussion by asking the TEP members if they were generally in favor of adding the PPPW and SWR measures. A TEP member asked if only those two transplant measures were under consideration, or would there be an option to add an alternative measure? It was clarified

that only the two transplant waitlist measures were up for consideration, and that either or both could be added to the Star Rating. A TEP member added that there should be a transplant measure in the Star Rating, but they were not sure which one should be added. The TEP member stated they preferred the PPPW over the SWR, based on the larger number of patients included in the PPPW denominator. This TEP member recommended the PPPW for consideration over the SWR and stated that the transplant referral measure under development by the Kidney Care Quality Alliance (KCQA) should also be considered in the future, subsequent to testing and full development.

Regarding the recommendation to consider a transplant referral measure, UM-KECC provided information about the 2014 Transplant TEP discussion and recommendations that considered a potential referral measure in addition to the waitlist measures recommended by that TEP. However, absence of national referral data and a validated referral measure has precluded any consideration at the current time. One TEP member agreed that a measure of transplant referral is more actionable for dialysis clinics. According to this TEP member, aside from the referral, there is not much a clinic can do to effect transplant rates.

A co-chair stated that it is important to remember the original purpose of the Star Rating as envisioned and articulated by CMS to the kidney community, including patients. It was to have a consumer-facing tool that would be easy to use and based on patient needs. A patient TEP member asked UM-KECC to clarify whether the PPPW includes in-center or home dialysis patients. The UM-KECC team confirmed that PPPW does include both home and in-center patients. Another TEP member added that when adding a new metric, it is important to consider potential unintended consequences on the Star Rating. According to this individual, aspects of the waitlisting process are outside a facility's control.

One TEP member asked if the addition of these two transplant measures would result in 4 domains with 25% weight each instead of the current 3 domains with 33% weight? UM-KECC responded that the current Domain 3 (Total Kt/V and Hypercalcemia) would receive half of its current weight, or half of 33%, in the updated methodology, per the recommendation of the 2019 TEP. The TEP member responded that the addition of a fourth domain would give more weight to the measures it contained (in contrast to inclusion of PPPW/SWR into a pre-existing domain), to which UM-KECC confirmed. In consideration of this, the TEP member confirmed that adding transplant measures as a separate domain has value, but if dialysis facilities have more control over some domains' outcomes versus others, they were uncertain how much the transplant domain should be weighted. The TEP member asked if UM-KECC had a figure/table to show the Star Rating of 3 domains, and then another table showing the relation to just the transplant domains, and how much correlation would there be between high transplant performance with the other measures/domains? The TEP member conveyed strong preference of considering the PPPW alone to considering both measures.

In response, UM-KECC described the original decision to equally weight domains when the Star Rating was first developed. The concern over differential weighting was whether consensus could be

obtained on the appropriate weighting for each measure included in the Star Rating. A policy decision was made by CMS at the time to equally weight each domain. The only exception to that policy was the later decision to down-weight the domain with Kt/V and hypercalcemia, based on the 2019 TEP consensus that the measures included in that domain retained little or no opportunity for improvement, but should not be omitted entirely to prevent "backsliding" in performance.

A TEP member commented that the reporting of waitlisting measures like the PPPW may get someone waitlisted but not necessarily a transplant. If everyone gets on the waitlist, but never gets a transplant, then it is not helping anyone. Another TEP member noted that transplantation is not important to all patients, and this particular measure would not be important for those patients not interested in transplantation. The suggestion was made that this information might be useful to a subset of patients, but might not be suitable for inclusion in the Star Rating, since it does not apply to all. Another TEP member agreed.

A TEP member commented that both measures are limited to those under the age of 75. The Star Rating is meant to provide information to all patients, and the TEP member added that they are a patient in a rural area, where 40-50% of the patients in their clinic are ineligible for a transplant due to their age. The TEP member voiced concerns that their facility would be adversely impacted by the Star Rating based on criteria they have no chance of meeting.

One co-chair specifically asked the physician TEP members if they would modify what they are recommending based on the patient consumer perspective presented during the preceding discussion about waitlisting versus a future referral measure. A TEP member added that if a patient is interested in transplant, then they would want to go to a dialysis facility that referred patients at a reasonable rate. The UM-KECC team estimated that inclusion of a referral metric would require, at a minimum, an additional 2-3 years.

A TEP member stated that everyone is supportive of the efforts to add a quality measure of transplant education, and anything that would improve patients' quality of life. They further added that transplant outcomes are usually driven by social and economic factors. Another TEP member said that they agreed with the conversation so far and that the measure(s) considered for inclusion should reflect the care delivered that is under the control of the dialysis unit, and they did not think either waitlist measure reflected that. This TEP member said they supported a referral measure in place of either wait listing measure. They stated that if the Star Rating is a tool for patients to use, then patients should be given helpful information, which means information on referrals.

A patient TEP member raised concerns about the two measures being discussed. One concern related to the lack of social and economic considerations. This TEP patient member was concerned that many rural clinics could be unfairly treated, because of the socioeconomic status of their patients. The individual also objected to the measures because some patients may not want a kidney transplant and the measures do not reflect that information (e.g., patient decision to not be placed on the

waitlist). Another TEP member agreed and noted that the new waitlist rules that extend waiting time to when chronic dialysis was initiated reduces the potential benefit of these measures.

A TEP member returned to the topic of domain weighting and expressed their difficulty in understanding what the facility has control over (and not) and how that is reflected in the measure results. A co-chair stated there are some facility processes of care reflected in measure outcomes that facilities can control, and some that they may not control. Despite these uncertainties in attribution of the measure outcome, it is important to create distinctions in performance between facilities so that patients and their families can easily make the most informed decisions about their care. A TEP member stated that they felt that mortality and waitlisting are patient-centered outcomes that are controlled by the facility. Another TEP member wondered if transplant rates would be a more palatable measure. The UM-KECC team commented that the 2014 Transplant TEP felt that transplantation was least attributable to the dialysis facility, although the outcome was more impactful. They recognized that referral was most attributable to the dialysis facility and waitlisting was intermediate. The 2014 TEP also discussed questions about the quality of patient education, when and how it often it was provided and how that could be defined.

A patient TEP member noted that they seek transparency from dialysis clinics. If information about kidney transplantation is available, it should be given to patients. Educating patients on what a transplant is and if it would be a good "fit" for them is important. As a patient, they pick their clinic based on what the facility offers to their patients. One of the co-chairs summarized these comments by re-stating people need information in order to form a proper conclusion.

A TEP member asked if the TEP was charged with considering one or both measures for inclusion, in order to narrow down the choices and focus the meeting moving forward. The co-chair further asked UM-KECC if they did the factor analysis based on including either one of the waitlisting measures, instead of both. UM-KECC offered to perform the factor analysis on each of the waitlisting measures prior to the next TEP meeting if it would help the TEP provide a final opinion about inclusion of neither, one, or both transplant waitlisting measures.

In order to provide some closure to the discussion and obtain a preliminary sense of the TEP's opinions, a preliminary vote was taken at close of the first teleconference meeting.

4.3 Vote

The TEP co-chairs proposed the question to the TEP on whether or not to include either transplant measure in an equal domain to the other domains. The TEP was asked to vote on the following question:

Question: "If you raise your hand in this vote, then you do not believe that either transplant measure should be considered further for consideration in the Star Rating. Please vote."

Results:

- 7 TEP members voted in the affirmative for ending considerations of either measure
- 5 TEP members voted for discussion after presentation of additional analysis
- 1 TEP member was absent

5. Continuation of Transplant Waitlisting Measures Discussion

5.1 Results of Additional Analyses

UM-KECC informed the impact of adding only one measure to the Star Rating, by presenting additional analysis results with three tables: one showing the impact of including only the PPPW, one showing the impact of including only the SWR, and one showing the impact of including both the PPPW and the SWR (see Appendix B for meeting slides).

In summary, the factor analysis results suggested that the transplant waitlisting measures, either alone, or both, formed a separate domain of care. Inclusion of only one waitlisting measure had a greater impact on changes in the Star Rating than the inclusion of both.

5.2 Discussion

The discussion began with one TEP member reminding the panel members that, ultimately, the Star Rating provides information to patients in order for patients to make decisions. If the objective is to increase transplantation, then this TEP member feels that the discussion of this particular TEP appears to be going in the opposite direction of that purpose. A co-chair asked for clarification of "going backwards". The TEP member re-stated the most important consideration is getting on the waiting list, and if patients cannot, then they will not receive a transplant.

Another TEP member asks the other panel members to consider this: if a patient picks a dialysis unit, should they use a metric that only reflects the care under the control of the dialysis clinic, or the entire transplant process? They continued that a referral measure would be a better measure, but they recognize that such a measure does not currently exist. The TEP member asked UM-KECC to bring the topic of referral to CMS for further discussion.

A TEP co-chair asked UM-KECC how long they anticipate it could take to develop a referral measure. UM-KECC responded that, at a minimum, it would take between another 2-3 years to create and adopt a new measure. UM-KECC also reminded the TEP that the development of a referral measure was not a question specifically for this panel, but those comments and opinions from the discussion would be reflected in the TEP Summary Report. UM-KECC reminded the current TEP that the 2014 Transplant TEP felt that referral alone was not enough, but that it was the most proximate measure in terms of the locus of control for dialysis facilities.

Another TEP member agreed that a referral-based metric that is within the dialysis center's control would be best. A TEP co-chair asked the TEP if any other TEP members wanted to make an additional comments. No other comments were made.

5.3 Vote

UM-KECC reminded the TEP to consider all opinions as they voted and that consensus would result from a supermajority (two-thirds). Three specific questions were posed to the TEP. The co-chair clarified that the TEP members could vote on each question. The voting results are below:

1. Do you recommend ONLY the SWR quality measure for inclusion in the Star Rating?
    a. Yes: 2 Votes
    b. No: 9 Votes
2. Do you recommend ONLY the PPPW quality measure for inclusion in the Star Rating?
    a. Yes: 2 Votes
    b. No: 9 Votes
3. Do you recommend inclusion of BOTH the PPPW and SWR quality measures in the Star Rating?
    a. Yes: 4 Votes
    b. No: 7 Votes

6. Baseline Period for the Star Rating

6.1 Introduction and Background

UM-KECC opened the discussion of the baseline period by summarizing the recommendations of the 2019 Star Rating TEP, which had recommended resetting the Star Rating to a 10% 5-star, 20% 4-star, 40% 3-star, 20% 2-star, 10% 1-star distribution. The 2019 TEP further recommended providing important educational and interpretation assistance to Care Compare users prior to release of the updated Star Rating based on the new methodology. Per the TEP charter, the 2022 TEP was charged with providing opinions and rationale for the use of a specific baseline period, if CMS made the policy decision to update the Star Rating for a future release. UM-KECC asked the TEP to consider three things when making this decision: (1) the timeliness and proximity of the baseline period to the current period of data reporting (2) the Extraordinary Circumstances Exception (ECE) data exclusions in 2020, and (3) the prevalence and impact of COVID-19. The TEP was presented with a summary of the considerations for each data year (Table 3).

Table 3: Baseline Period Considerations

Period	COVID-19	Data Reporting	Timeliness
CY 2019	Data Collected Prior to COVID-19 Pandemic	Complete Data	Least Proximate
CY 2020	Data Collected During Initial COVID-19 Surges	ECE Exemptions	More Proximate
CY 2021	First Full Year of Data During COVID-19 Pandemic	Pending	Most Proximate

In addition, UM-KECC requested that TEP members share any additional considerations about the choice of a baseline period, particularly given the inability to present complete 2021 data at the time.

6.2. Impact of COVID-19 on Star Rating Measures and Data

A brief background on the Extraordinary Circumstances Exception (ECE) policy, established in response to the COVID-19 public health emergency, was presented to the TEP. Specifically, on March 27, 2020, CMS released guidance describing the scope and duration of the ECE granted under each program. Under this guidance, providers were relieved of their obligation to report clinical data for the first two quarters of calendar year 2020. Additionally for claims-based measures, claims data from March 1- June 20, 2020 would be excluded from measure calculations.

UM-KECC presented analyses which evaluated the impact of COVID-19 on the quality measures reported on Care Compare from 2020, including patient counts, deaths, and hospitalizations among Medicare dialysis patients in 2020 (see Appendix B for meeting slides).

Patient Mortality

The results presented showed that all-cause mortality rates for ESRD patients were significantly higher in 2020 than in previous years, with peaks in April, July, and December, consistent with known waves of the pandemic in the general population. In addition, the risk of COVID-19 was higher among Black and Hispanic patients, patients living in urban areas, and patients in nursing facilities. The results also highlighted that existing risk factors for mortality (e.g., older age, male sex, and diabetes) were also associated with higher post-COVID-19 infection mortality.[1]

Hospitalization and Readmission

The results presented to the TEP showed the association between the onset of the COVID-19 pandemic and all-cause hospitalization hazards (number of admissions/number at risk), among Medicare dialysis patients, from January 1, 2018 to December 31, 2020. There was a rapid reduction in hospitalization rates of about 20% in March 2020, which subsequently returned to normal levels in July 2020. The trend in 2020 differed from 2018 and 2019, despite an expected seasonal decline in hospitalization rates from January to June. This information suggested a perturbation in hospital utilization, which may have resulted in adverse outcomes among non-COVID-19 patients. Despite a reduction in hospitalizations in the second quarter of 2020, additional analyses demonstrated increase hospitalization risk associated with COVID-19 infection in Medicare dialysis patients.

The TEP was presented with results that showed death and 30-day readmissions increased for those patients discharged following a COVID-19 hospitalization, but the impact of COVID-19 abated after 7-8 days post-discharge. Both higher death rates and lower readmission rates among patients with a

[1] Salerno S, Messana JM, Gremel GW, et al. COVID-19 Risk Factors and Mortality Outcomes Among Medicare Patients Receiving Long-term Dialysis. *JAMA Netw Open*. 2021;4(11):e2135379. doi:10.1001/jamanetworkopen.2021.35379

COVID-19 index discharge suggested potential competing risks of death or discharge to hospice, both of which would remove them from the denominator of the SRR.

Additional Measures and Baseline Period Considerations

The TEP was shown results for additional outcomes:

- Transfusion Ratio: After an initial decline in spring 2020, there were no significant changes in transfusion rates (per patient) for the remainder of 2020.
- Waitlisting and Removal: Removal for any cause and new patient waitlist addition were perturbed in the second quarter of 2020, compared to prior years. This generally returned to normal in June/July 2020. Of note, little or no effect on PPPW and SWR was noted during this time period.
- Hypercalcemia and Kt/V: UM-KECC observed small, but detectable increases in missing values for hypercalcemia and PD Kt/V in March-June 2020, with no change in reporting of HD Kt/V, and no change in patients achieving the calcium or HD Kt/V targets.
- Vascular Access: There was a small, but notable, increase in long-term catheter use and a corresponding decrease in AV fistula use in March, April, and May 2020, compared to the same months in 2019.

A co-chair asked UM-KECC when the 2021 data would be released to the public. UM-KECC replied that 2021 data had not been released for several reasons, most importantly that the data were not yet complete, based on reports of a backlog in information entry to the national reporting system.

6.3. Discussion

A TEP member asked if the options for the baseline period had to be defined by calendar year boundaries. UM-KECC responded that calendar year boundaries were preferred. The TEP member responded with a concern that calendar year boundaries could be problematic because of the geographic variation in the various waves of the pandemic.

Another TEP member commented that there was not one right answer because each scenario (i.e., potential options for a baseline year) had pros and cons. The TEP member stated that the Star Rating was not meant to assess quality of care during a pandemic, suggesting that 2021 may not be a good baseline year, because it would not really reflect the quality of care provided the dialysis facility given the impact of the pandemic on care delivery. However, 2019 would be a pre-pandemic baseline, which could also be considered an unfair standard.

A TEP member suggested that 2019 would be the best option compared to the other proposed baseline years, as COVID-19 impacted the country in different ways, meaning that there were many facilities that were generally able to deliver care as usual. Another TEP member asked whether there would be an option to not rebaseline at all and consider measure suppression instead. UM-KECC reminded the TEP that suppression had already occurred for the prior planned star rating updates

(October 2020 and on). Moreover suppression is a policy decision and not a specific topic for the TEP discussion and vote.

A patient TEP member said the best option for the baseline period would be 2019 because it removes the devastating impact of the pandemic, by using a pre-pandemic year as baseline. Another TEP member agreed with 2019 because data from 2020 and 2021 would be highly impacted by COVID-19, and patient behaviors drastically changed as well.

A TEP member expressed concern about lack of patient access to the 2020 data that clinics were given. Another TEP member agreed that patients should be informed of the clinical measure results and the data should be presented to patients. A TEP member stated that there may be some distrust when looking at the Star Rating without having a means of accounting for COVID-19. As an example, some patients had to change dialysis clinics if they had COVID-19 (i.e., due to some clinics cohorting COVID patients). One member asked about the possible inclusion of COVID-19 risk adjustment or, at least, a regional COVID-19 impact factor for reporting.

6.4. Vote

UM-KECC proposed that TEP members voted on which baseline period to recommend.

Question: "Please indicate which of the calendar years (2019, 2020, or 2021) would be best to use as the baseline if the Star Rating was reset?"

Results:

- 2019: 6 Votes
- 2020: 2 Votes
- 2021: 3 Votes

7. TEP Member General Discussion

UM-KECC invited the TEP to have an open discussion if there was anything additional they would like CMS to hear about the Star Rating. TEP members noted the importance of communicating data on the impact of COVID-19 on dialysis treatment to patients/consumers.

- One TEP member noted that while it would be important to publically report data during the COVID-19 pandemic, it would be important to properly contextualize these results.
- A TEP Co-Chair agreed COVID-19 data should be publically reported, with contextualization, at the facility level- including mortality data because patients are intelligent enough to understand data and context and would still find it important.
- Several TEP members felt that COVID-19 will likely not be the last pandemic the country will face, and knowing how dialysis facilities reacted to the challenges they faced (through their performance) could be important information for patients to consider.

- It was noted that patients' experiences during the pandemic could have varied widely depending on their particular circumstances, so knowing how their facility performed on these metrics would be important.

8. Public Comments

Comment from Kathy Lester, to Lester Health Law, PLLC
Kidney Care Partners
February 2022
First TEP meeting comment

Thank you again for the opportunity to listen into the February 17 TEP discussion and provide thoughts on the question of adding a transplant measure to the ESRD Five Star Program. As you know, I work with Kidney Care Partners (KCP). KCP is an alliance of members of the kidney care community that serves as a forum for patient advocates, dialysis care professionals, providers, and manufacturers to advance policies that support the provision of high-quality care for individuals with chronic kidney disease (CKD), including End-Stage Renal Disease (ESRD).

KCP strongly supports providing patients with greater transparency in regard to transplantation, as we have shared with CMS in our comments in the recent kidney transplant ecosystem Request for Information. KCP has acted on this support by convening the Kidney Care Quality Alliance (KCQA) to develop transplants measures that CMS could adopt to provide individuals on dialysis and their care partners with information about how facilities support transplantation.

This work has resulted in the creation of a referral measure that would accompany a counterbalancing waitlist measure. KCQA is in the process of testing this measure set and plans to submit it to NQF for endorsement during the next cycle (August 2021). Early indications suggest that both will be reliable and valid.

Listening to the patients and physicians, as well as the facility representatives, during the TEP discussion, it was clear that there is agreement that an actionable referral measure is much preferred to a waitlist measure.

The PPPW and the SWR are problematic, and the NQF has not endorsed either. These measures provide no insight into how a dialysis facility is performing to support patients who are seeking a transplant. They only tell whether a transplant center has accepted patients, which is not helpful in selecting a dialysis facility.

It appears from the timeline described during the TEP discussion, there is time for CMS to work with the KCQA as its transplant measure set moves through NQF later this year and adopt these measures for Five Star.

We recognize that there is not yet perfect national data on referrals. KCP continues to ask HHS to require transplant centers to send confirmation information about referrals to dialysis facilities generally. However, until such requirements are in place, KCQA has identified data elements that will support a referral measure and that could be audited to confirm accuracy in reporting and subsequently incorporated into the EQRS system. Having an actionable measure is too important to wait on having perfect data.

Given the problems with the PPPW and SWR measures and the importance of having a transplant measure, KCP urges the TEP to recommend that CMS engage with the KCQA to adopt its transplant measure set in Five Star. At the same time, the TEP should urge CMS to work with its sister agencies to develop a national data source to improve communications between transplant centers and facilities and that included data that could be used in a revised referral measure in the near future.

KCP remains committed to supporting performance transparency. It is important that the measures in Five Star reflect the actual performance of facilities. Any measure that does not, should not be included, especially when there is an alternative measure that meets the actionability criterion available.

KCP also looks forward to future discussions about how adding a measure will affect the methodology used to assign star ratings.

Thank you again for the opportunity to provide comments.

Comment from Kathy Lester, to Lester Health Law, PLLC
Kidney Care Partners
Second TEP meeting comment

"Thank you Joe, and thank you to all TEP members, and I echo what Joe said that it's really great to hear the conversation and be able to listen in on these incredible issues. I think you all know, I work with Kidney Care Partners, which is a large umbrella organization for 30 different types of entities in the health care area, including patient advocate facilities, innovative companies, manufactures and healthcare professionals. As you know with KCP, as we've gone through the last several years transplant measures have become more and more of a priority for us. As we have noted in our comments that were wrote last week, sorry about my scheduling, we've supported the development of a referral metric in a measure set, and also, with a waitlist measure, and that is, you know, hopefully where we will be able to help inform this discussion as well. As many have said, it is important to remember the purpose of the five star program, and that is to give patients and caregivers a tool to decide where they can best receive their facilities care, and I think what we heard today is what we've

heard through KCP and the patient groups there is that wait listing measures do not provide the information about facilities actual performances. The vote today shows that the vast majority of this TEP also does not think that with the SWR and the PPPW separately or together really have that important meaningful measure that reflects the action of facilities. I think our concern is locking in the wrong measure, because it is very hard to move measures in and out of programs. So KCP has raised the money to have the KCP develop a measure we anticipate submitting that measure into the upcoming fall, and it is being tested right now. That referral measure is with a set, as I said, with a waitlist metric that would allow patients to have the information about what the facility actually does to support transplant for their patients, which I think is what we're hearing patients really want to know. I do think we can address concerns around that, you know, having access to data and I encourage the CMS members on this call who work with you and your team on how we can work with others within transplant centers consisted with what was put out earlier this year to get that data and make it available given where we are. I would ask that in the report, you could specifically state that it is important to include transplant measures in the five star program but that measure needs to be a referral metric that provides information about the facilities actual performance so patients can make those informed decisions, and that is important for CMS to support those developing a referral measure quickly. In terms of the best data year, I think it's something we all struggle with, but I think what the conversation, to me today showed, that it's not the time to reset the ratings. The pandemic has really distorted the data and I do think it's important to understand where we have been. Joe, you mentioned that sources, and I was going to mention, you know there are many papers out there, what CMS has been doing and updating patients in the community about what's going on but when you look a the data it is very problematic, and I will say as a caregiver for my elderly mother, I would find it very difficult to tease out what is something that a facility is going wrong, and what is something a facility is doing right. What is due to the pandemic, and out of our control, and what is not, so I do think we want to make sure that, until we do something like that, that we don't create what for some patients could be a great deal of fear or confusion and we know for some of the early days of the five star program there as confusion. Patients were scared to go to facilities that had one or two star ratings, we certainly don't want to go back to those days. SO in summary I am encouraged by the thoughtfulness of the TEP today and I think it's important that we take the clear message from the patients and providers and the healthcare professionals who sit on this TEP, and that we do not need a transplant measure that reflects those actions that facilities and KCP really would support and offer the opportunity to work with everyone to get one of those referral measures here sooner rather than later. Thank you."

9. Appendices

A. TEP Charter
B. TEP meeting slide presentations

Technical Expert Panel Charter

Project Title:

Dialysis Facility Quality of Patient Care Star Ratings Technical Expert Panel (TEP)

TEP Expected Time Commitment and Dates:

We anticipate the TEP will consist of 2-3 meetings all held via a secure video conferencing platform (e.g., Zoom). The duration of each meeting will be between 1 to 4 hours. Meetings are tentatively scheduled to begin February 2022 with subsequent meetings occurring between March and April 2022.

Project Overview:

The Centers for Medicare & Medicaid Services (CMS) has contracted with The University of Michigan Kidney Epidemiology and Cost Center (UM-KECC) to act as the quality measure developer and technical content support contractor for Care Compare on Medicare.gov, under the Kidney Disease Quality Measure Development, Maintenance, and Support contract (contract number 75FCMC18D0041, task order number 75FCMC18F0001). As part of this contract, UM-KECC convenes technical expert panels (TEPs) to obtain consumer and provider input for quality measure development and the Medicare.gov Dialysis Facility Quality of Patient Care Star Rating (Star Rating). We seek nominations from individuals with relevant clinical and methodological experience, expertise, and perspectives, including ESRD patients with dialysis experience to serve on this TEP.

A Star Rating TEP was first convened in 2015 to review the original methodology and presentation of the Star Rating on the Medicare.gov website. The TEP provided several recommendations that were implemented in the updated Star Rating methodology, released in October 2016. A second TEP was convened in 2017. TEP members provided recommendations on candidate measures proposed for inclusion in the Star Rating and defined concepts such as rebaselining and resetting. A third TEP was convened in 2019 to provide recommendations on options for resetting the Star Rating and reweighting one of the quality domains in the calculation of the Star Rating. See the respective 2015, 2017, and 2019 Star Rating TEP reports for a summary of the deliberations and TEP recommendations, available at:

https://dialysisdata.org/content/esrd-measures

As part of CMS' broader initiative for Care Compare on Medicare.gov, CMS developed the Star Rating to make quality information more accessible to patients, caregivers, providers and policymakers and to help consumers (including patients and caregivers) understand CMS quality measures and more easily identify differences in overall quality when selecting dialysis facilities. The Medicare.gov website displays two star ratings: (1) the Quality of Patient Care Star Rating (Star Rating) and (2) the Survey of Patients' Experiences Star Rating. Eleven of the quality measures currently reported on the Medicare.gov website are used to calculate the Quality of Patient Care Star Rating (Star Rating). The Survey of Patients' Experiences Star Ratings will not be covered as a discussion topic during this TEP. Broadly, this TEP will be expected to review and provide input on options and considerations for updating and public reporting of the Star Ratings. These considerations fall under three categories:

(1) Adding two quality measures currently reported on the Medicare.gov site related to transplant waitlisting to Star Rating (PPPW and SWR)

(2) Choice of a calendar year to use for establishment of a new baseline against which to score facility performance

(3) Potential of public reporting of the continuous score underlying Star Rating on Medicare.gov in addition to the Star Rating, which places facilities into one of five discrete categories.

The TEP will be expected to represent a diversity of perspectives and backgrounds. Members will be selected based on their personal experience as patients, caregivers and providers, or based on methodological expertise. Our intent is to ensure the TEP will have ample representation from patients and patient advocates to allow fair representation of their perspectives.

Project Objectives:

UM-KECC, through its contract with CMS, will convene a TEP to obtain recommendations related to the first public release of the Star Rating since the start of the COVID-19 pandemic public health emergency. Input from the TEP will inform expansion of the measure set used in the Star Rating, establishment of a new baseline period, and potential reporting of a continuous Star Rating score on Medicare.gov. The final methodology developed is intended to ensure that the Star Rating continues to be informative by reflecting meaningful performance differences among facilities.

Technical Expert Panel (TEP) Objectives:

The 2022 Star Rating TEP is expected to focus on:

1. Providing recommendations on the addition of two measures related to transplant waitlisting
2. Establishment of a new baseline against which to score facility performance related to considerations of the impact of COVID-19 on data reporting and ESRD dialysis outcomes
3. Discussing the potential public reporting of a continuous Star Rating score on Medicare.gov

TEP Requirements:

A TEP of approximately 12-20 individuals will meet to discuss and provide recommendations on the above topics to UM-KECC. The TEP will be composed of individuals with differing expertise and perspectives, including:

- Individuals with end-stage kidney disease and caregivers of individuals with ESRD
- Experts with subject matter expertise, e.g., scientists in nephrology care; clinicians and nurses; consumer testing; communication of star rating systems from the patient perspectives
- Experts with methodological expertise, e.g., statisticians/biostatisticians with expertise in score or scale development, multivariate analysis, risk assessment, latent variable modeling
- Individuals with dialysis facility quality improvement expertise
- Individuals with health care disparities expertise

Scope of Responsibilities:

UM-KECC is seeking balanced representation of dialysis stakeholders and clinical experts, including patients and patient-advocates, dialysis providers, as well as clinical, statistical, and public health experts

to provide input on the topics described above. The TEP will be led by one or two Chairpersons, whose responsibility is to lead the discussion and attempt to develop consensus opinions from TEP membership regarding discussion topics. The TEP is intended to be advisory to UM-KECC, as UM-KECC continues to develop and refine the star ratings.

The role of each TEP member is to provide advisory input to UM-KECC.

Role of UM-KECC: As the CMS measure development contractor, the UM-KECC moderators will work with the TEP chair(s) to ensure the panel discussions focus on the review of draft measure specifications, as recommended by the contractor. During discussions, UM-KECC moderators may advise the TEP and chair(s) on the needs and requirements of the CMS contract and the timeline, and may provide specific guidance and criteria that must be met with respect to CMS policy. UM-KECC will prepare a summary report of the TEP proceedings. UM-KECC is responsible for ensuring that the summary report accurately reflects the TEP discussion and recommendations. Although the TEP is advisory only, it is important that CMS is informed of the TEP's recommendations in an objective fashion.

Role of TEP chair(s): Prior to the TEP meetings, one or two TEP members are designated as the chair(s) by the measure contractor and CMS. The TEP chair(s) are responsible, in partnership with the moderator, for directing the TEP to meet the expectations for TEP members, including provision of advice to the contractor regarding methodological issues.

Duties and Role of TEP members: According to the CMS Measure Management System Blueprint, TEPs are advisory to the measure contractor. TEP members are expected to attend conference calls in 2022 and be available for additional follow-up teleconferences and correspondence as needed. The TEP will review, edit (if necessary), and adopt a final charter at the first teleconference. A discussion of the overall tasks of the TEP and the goals/objectives of the project will be described. The key deliverable of the TEP meetings includes a summary report documenting the discussions and proposed recommendations that are made during the in-person meeting.

Guiding Principles:

Participation as a TEP member is voluntary and the measure developer records the participant's input in the meeting minutes, which the measure developer will summarize in a report that they may disclose to the public. If a participant has chosen to disclose private, personal data, then related material and communications are not covered by patient-provider confidentiality. Patient/caregiver participants may elect to keep their names confidential in public documents. TEP organizers will answer any questions about confidentiality.

The TEP may use both verbal consensus and formal voting by secret ballot for decision-making, depending on the context of the decision. For administrative and other decisions about agenda, direction of discussion, and other minor operational decisions, informal verbal consensus directed by the TEP chair(s) will be utilized. In order to objectively record TEP recommendations about the validity of the quality measures presented and recommended changes, formal votes will utilize secret ballots.

All potential TEP members must disclose any significant financial interest or other relationships that may influence their perceptions or judgment. It is unethical to conceal (or fail to disclose) conflicts of interest. However, there is no intent for the disclosure requirement to prevent individuals with particular

perspectives or strong points of view from serving on the TEP. The intent of full disclosure is to inform the measure developer, other TEP members, and CMS about the source of TEP members' perspectives and how that might affect discussions or recommendations.

Estimated Number and Frequency of Meetings:

Two to three meetings all held via a secure video conferencing platform (e.g., Zoom). The duration of each meeting will be between 1 to 4 hours. Meetings are tentatively scheduled to begin February 2022 with subsequent meetings occurring between March and April 2022.

Date Approved by TEP:

TBD

TEP Membership:

TBD

SCHOOL OF PUBLIC HEALTH
KECC
UNIVERSITY OF MICHIGAN

Dialysis Facility Quality of Patient Care Star Ratings Technical Expert Panel (TEP)

TELECONFERENCE CALL #1

FEBRUARY 17, 2022 · 1PM – 4PM, EST

Discussion Reminders

- Use the ‘raise hand’ function if possible
- Share questions and ideas directly during discussion
- Refrain from using the chat
- Mute yourself when not speaking, unmute when needed
- Public participants may speak at end of the meeting during the allotted public comment period

TEP Meeting #1 Agenda

1:00 PM:	TEP Member, CMS, and UM-KECC Introductions
1:15 PM:	TEP Overview and Charter Approval
1:25 PM:	Presentation on Transplant Waitlist Measures
2:10 PM:	TEP Discussion and Consensus Recommendation or Vote
2:55 PM:	Public Comment

UM-KECC Star Rating Team

Name and Credentials	Organizational Affiliation	Conflicts of Interest
Yi Li, PhD	Professor, Biostatistics Professor, Global Public Health	None
Joseph Messana, MD	Professor, Internal Medicine, Division of Nephrology Research Professor, Health Management and Policy	None
Claudia Dahlerus, PhD	Assistant Research Scientist, Internal Medicine, Division of Nephrology	None
Richard Hirth, PhD	S. J. Axelrod Collegiate Professor, Health Management and Policy Professor, Internal Medicine	None
Peisong Han, PhD	Associate Professor, Biostatistics	None
Wolf Gremel, MS	Senior Analyst	None

UM-KECC Star Rating Team

Name and Credentials	Organizational Affiliation	Conflicts of Interest
Tao Xu, PhD	Senior Analyst	None
Casey Parrotte, BA, PMP	Continued Improvement Specialist Lead	None
Jennifer Sardone, BA, PMP	Senior Lead Project Manager	None
Eileen Yang, BS	PhD Student, Biostatistics	None
Stephen Salerno, MS	PhD Student, Biostatistics	None
Jaclyn George, AA	Project Manager **Point of Contact:** jaclynrg@umich.edu	None

CMS Representatives

- Golden Horton, MS
- Wilfred Agbenyikey, ScD

TEP Introductions and COI

- TEP members must disclose any current and past activities that may cause a conflict of interest. This includes financial interests or other relationships that may influence their perceptions or judgement.
- It is unethical to fail to disclose any perceived or real conflicts of interest. However, the disclosure requirement is not intended to prevent individuals with particular perspectives or strong points of view from serving on the TEP.
- The intent of full disclosure is to inform the measure developer, other TEP members, and CMS about the source of TEP members' perspectives and how that might affect discussions or recommendations.
- If a member's status changes and a potential conflict of interest arises at any time while a member is serving on the TEP, the TEP member is required to notify the measure developer and the TEP chair.

TEP Members

Name and Credentials	Organizational Affiliation	Conflicts of Interest
Paul Conway, BA*	Chair of Public Policy and Global Affairs American Association of Kidney Patients	No
Nicole Stankus, MD, MSc*	Nephrologist University of Chicago	No
Andrew Conkling	President of Board of Directors Dialysis Patient Citizens	No
Mary Dittrich, MD, FASN	Nephrologist, Chief Medical Officer US Renal Care	Shareholder, CMO of US Renal Care, Shareholder, multiple dialysis units
Stephanie Dixon	Patient National Forum of ESRD Networks	No
Nupur Gupta, MD	Physician, Assistant Professor of Clinical Medicine Indiana University School of Medicine	No

**Co-Chair for the 2022 Star Rating TEP*

TEP Members

Name and Credentials	Organizational Affiliation	Conflicts of Interest
Emel Hamilton, MD, MSN/INF, CNN	Vice President of Clinical Support and Clinical Informatics, Non-practicing physician, RN License Fresenius Medical Care	Employed by Fresenius Kidney Care
Syed Ali Husain, MD, MPH MA FASN	Assistant Professor of Medicine Columbia University Medical Center	No
Richard Knight, MBA	President American Association of Kidney Patients	No
Mahesh Krishnan, MD, MPH, MBA, FASN	Group Vice President, Research and Development DaVita Kidney Care	Employed by DaVita, Shareholder
Diane Morris, MS, RN, CNN	Director of Nursing and Clinical Services The Rogosin Institute	No
Curtis Warfield, MS	Board of Directors Member National Kidney Foundation, Home Dialyzers United	No
Eric Weinhandl, PhD, MS	Sr. Director, Data Analytics and Home Therapies Satellite Healthcare	Employed by Satellite Healthcare

Role of the TEP

- Review evidence to determine the basis of support for the proposed update(s) related to topics identified in the TEP charter
- Review and approve summary report of the TEP Meeting and provide input on other necessary technical documentation required for public reporting or for responses to public comments
- Be available for follow up conference calls, as needed

Role of the TEP

- TEPs are advisory to the contractor (UM-KECC), and not CMS
- It is the responsibility of UM-KECC to accurately report AND consider recommendations received from the TEP; however recommendations made to CMS are made by UM-KECC, and not by the TEP
- If UM-KECC makes recommendations to CMS that are not consistent with the recommendations from the TEP, it is UM-KECC's responsibility to explain the rationale for any differences

Role of the TEP Chairs

- The TEP chairs are responsible, in partnership with UM-KECC, for directing the TEP to meet its expectations, including provision of advice to the developer/contractor regarding methodology updates to the Star Rating
- Conduct the meeting according to the agenda
- Recognize speakers and call for votes when needed

Role of UM-KECC

- Support the development of methods that are used in CMS quality programs for public reporting
- Work with the TEP chairs to ensure the panel discussions focus on the proposed methodological updates, as recommended to the developer/contractor
- Advise the TEP and the TEP chairs on the needs and requirements of the CMS contract and the timeline, and provide specific guidance and criteria that must be met with respect to CMS review of methodological updates

TEP Objectives

The 2022 Star Rating TEP is expected to focus on:

1. Providing recommendations on the addition of two transplant waitlist measures
2. Establishing new baseline criteria for updating the Star Rating and discussing the impact of COVID-19 on reporting and patient outcomes
3. Discussing the potential public reporting of a continuous Star Rating score on Medicare.gov

Questions

ANY TEP QUESTIONS ABOUT THE CHARTER AND OBJECTIVES?

Star Rating Overview

The Centers for Medicare & Medicaid Services (CMS), through a contract with UM-KECC, developed the Dialysis Facility Quality of Patient Care Star Rating System (Star Rating):

- To rate the quality of care provided by dialysis facilities
- To provide patients, families, and caregivers information to easily compare dialysis facilities

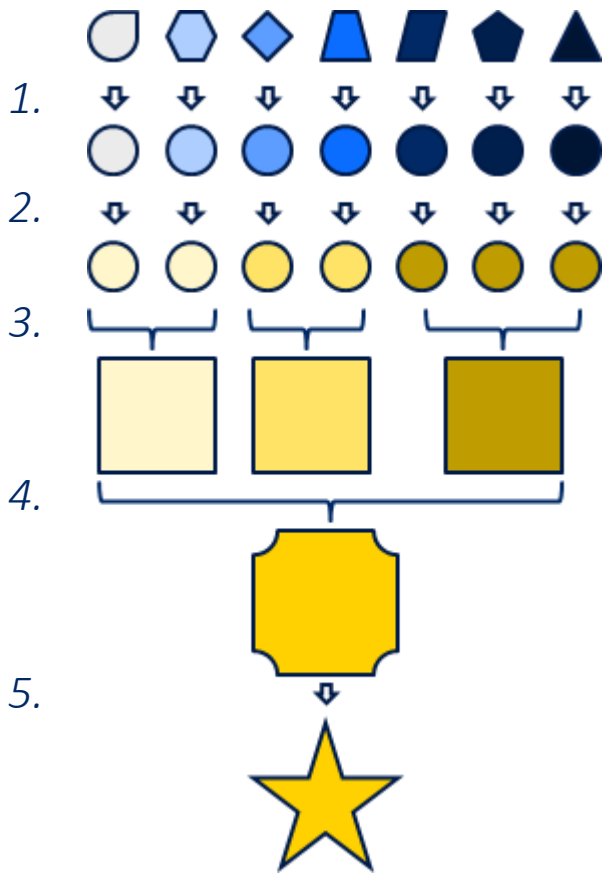
Since the Star Rating was first released in January 2015, UM-KECC has facilitated three TEPs to provide recommendations on updates to the Star Rating methodology

Key Concepts and Terminology

Term	Definition
Measure Value	The original value of a facility's clinical quality measure as reported on DFC, which represents a ratio or a percentage
Measure Score	A standardized score applied to a specific measure, so that no measure has undue influence on the Star Ratings, and so that the range and direction of scores are consistent (mean 0, variance 1)
Domain Score	A score which summarizes a facility's performance on a group of correlated clinical quality measures. It is an average of the individual measure scores in that group (domain)
Final Score	A continuous score calculated for each facility, which summarizes its performance on the reported clinical quality measures. It is an average of the three domain scores
Cutoff	A value of the final score that defines the boundary between two adjacent Star Rating categories (e.g., the cutoff between 4- and 5-stars is 1.36 and facilities with a final score > 1.36 receive 5 stars)

Star Rating Overview

1. *Measure values* on different scales are standardized against a *baseline period* to form *measure scores* with the same interpretation
2. *Individual measures* are grouped into different measure domains based on their correlations
3. *Measure scores* within a domain are averaged to form *domain scores*
4. *Domain scores* are averaged to form a *final score* for each facility
5. *Final scores* are grouped into five star categories based on pre-established Star Rating *cutoff* values



Key Concepts and Terminology

Term	Definition
Baseline Period	The time period (e.g., calendar year) in which data are collected for computing measure scoring criteria and defining cutoff values for Star Rating categories. The cutoffs will be used to rate facilities in future evaluation periods
Evaluation Period	The time period (e.g., calendar year) in which data are collected for calculation of measure results and facility Star Rating scores, reported on DFC. Final scores in the evaluation period are compared against cutoffs established in the baseline period in order to rate facilities
Rebaselining	Establish a new baseline period and scoring cutoffs. These cutoffs let the Star Rating distribution remain unchanged from the past release to allow for continuity over time when updating measures
Resetting	Establish a new baseline period, scoring cutoffs, and Star Rating distribution. These cutoffs define a new Star Rating distribution to better differentiate facility performance

Rebaselining vs. Resetting

Rebaselining: establish a new baseline, recalculate final scores, and define new cutoffs to accommodate changes to the measure set

Resetting: define cutoffs to reset the entire Star Rating distribution

When to Rebaseline:

- When measures are added or removed
- When current measures are updated

When to Reset:

- When the Star Rating distribution is significantly compressed
- When information provided is no longer useful in discriminating facility performance

Current Star Rating Measures

Domain	Measure
1	Standardized Transfusion Ratio for Dialysis Facilities (STrR)
	Standardized Mortality Ratio for Dialysis Facilities (SMR)
	Standardized Hospitalization Ratio for Dialysis Facilities (SHR)
	Standardized Readmission Ratio for Dialysis Facilities (SRR)
2	Hemodialysis Vascular Access: Standardized Fistula Rate (SFR)
	Hemodialysis Vascular Access: Long-Term Catheter Rate (LTC)
3	Total Kt/V (Kt/V)*
	Proportion of Patients with Hypercalcemia (Hyp.)

**Four Kt/V measurements (adult/pediatric, HD/PD) are combined into a single, Total Kt/V measure*

Adding Transplant Waitlist Measures to the Star Rating?

PRESENTATION AND ANALYSIS RESULTS

Transplant Waitlisting and Facilities' Roles

- Kidney transplantation often results in a longer and higher quality life, and waitlisting is necessary for certain patients to receive a transplant
- Transplant waitlisting has shared accountability among several provider groups. Dialysis facilities can influence the referral, pre-transplant medical evaluation, and health status of patients during the evaluation and listing period
- Facilities vary in their patients' success in accessing kidney transplantation, even after risk adjustment
- Two measures of transplant waitlisting are currently publicly reported on Medicare.gov and can be considered for inclusion in Star Rating

Two Transplant Waitlist Measures

1. Standardized First Kidney Transplant Waitlist Ratio for Incident Dialysis Patients (SWR)
2. Percentage of Prevalent Patients Waitlisted (PPPW)

Standardized First Kidney Transplant Waitlist Ratio (SWR) for Incident Dialysis Patients

Measure Definition: *Observed / Expected Waitlisting Number*

Numerator: Number of patients on the transplant waitlist or who received transplants within the first year of dialysis

Denominator: The expected number of waitlisting or transplants within the first year of dialysis, adjusted for age and incident comorbidities

Domain: Care Coordination

Interpretation: Higher Rate Desired **Measure Type:** Process

Percentage of Prevalent Patients Waitlisted (PPPW)

Measure Description: Proportion of patient-months at each dialysis facility that patients were on the transplant waitlist

Numerator: Number of patient-months at the dialysis facility and on the waitlist

Denominator: All patient-months assigned to a dialysis facility according to each patient's treatment history

Domain: Care Coordination

Interpretation: Higher Rate Desired **Measure Type:** Process

Evaluation of Adding Waitlist Measures to Star Rating

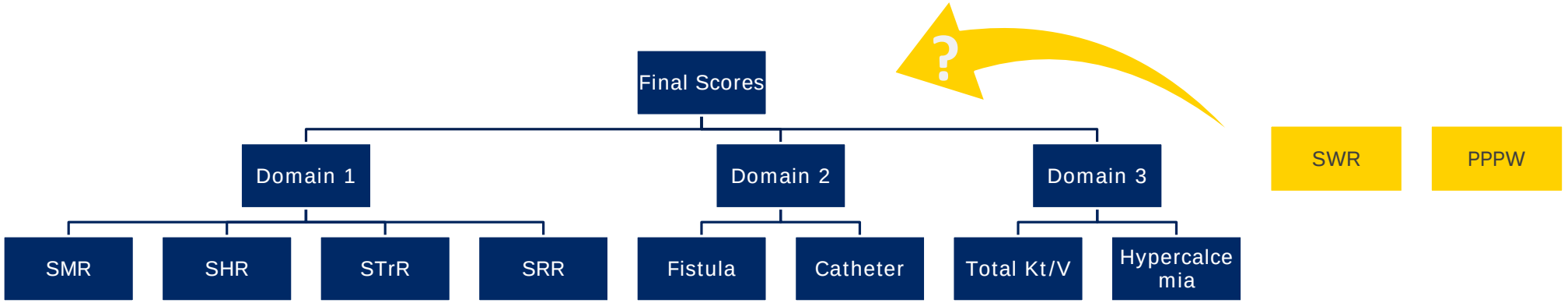
- When new measures are added to the Star Rating, the measure domains must be reassessed, e.g., to put new measures into existing domains or create new domains
- Star Rating must be *re-baselined,* i.e., to recalculate final scores and create new cutoffs for defining stars
- We conducted an analysis to inform these considerations using data corresponding to the October 2020 release, projecting what would happen in future updates

Why group measures into different domains?

- Avoid a single measure or groups of correlated measures dominating the Star Rating
- Let Star Rating reflect various aspects of care

How to group these measures?

We group measures based on their correlations using a statistical approach known as *factor analysis*



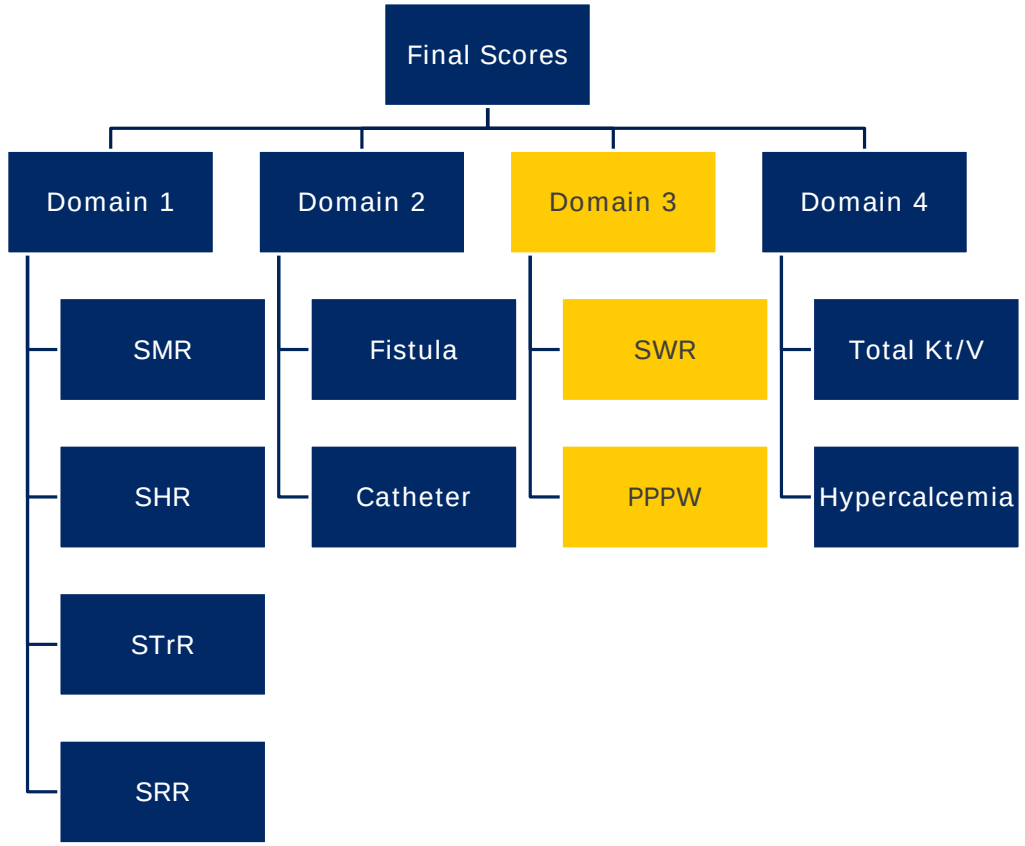
Correlations among the Measures

Measure	STrR	SHR	SMR	SRR	SFR	LTC	Hyp.	Kt/V	SWR	PPPW
STrR	1.00	-	-	-	-	-	-	-	-	-
SHR	0.35	1.00	-	-	-	-	-	-	-	-
SMR	0.17	0.20	1.00	-	-	-	-	-	-	-
SRR	0.17	0.41	0.10	1.00	-	-	-	-	-	-
SFR	0.09	0.14	0.08	0.08	1.00	-	-	-	-	-
LTC	0.11	0.18	0.09	0.08	0.46	1.00	-	-	-	-
Hyp.	0.05	0.09	0.08	0.03	0.16	0.22	1.00	-	-	-
Kt/V	0.15	0.19	0.13	0.09	0.18	0.26	0.28	1.00	-	-
SWR	0.04	0.05	0.08	0.02	0.12	0.03	0.01	-0.03	1.00	-
PPPW	0.06	0.08	0.11	-0.01	0.15	0.07	-0.06	-0.10	0.42	1.00

Impact of Adding Transplant Measures

Factor analysis results suggests that:

- The transplant waitlist measures create a new and separate domain
- The current domains would not change as a result of adding the transplant waitlist measures
- Star Ratings may provide additional quality information on a separate important aspect of care, e.g. transplant accessibility



Star Rating Agreement

Current 3 Domains	4 Domains with Transplant Waitlisting Measures				
	★	★★	★★★	★★★★	★★★★★
★	**7.4%**	2.1%	0.3%	0.1%	-
★★	2.5%	**12.2%**	5.0%	0.2%	-
★★★	-	5.6%	**27.2%**	6.0%	1.1%
★★★★	-	0.1%	7.2%	**9.6%**	3.2%
★★★★★	-	-	0.2%	4.1%	**5.7%**

No. Rated = 7,009; No. Unrated = 680

Star Rating Agreement Results

- 62.2% of facilities received the same rating under the two Star Rating systems (with and without waitlisting measures)
- 37.8% changed ratings with the addition of the transplant waitlist measures
- The weighted agreement (κ) statistic was 67%, suggesting moderate agreement between the two Star Rating systems

Summary of Results

- Most facilities are rated the same (62.2%) with the additional of the transplant waitlisting measures
- 35.7% rated either one star higher or lower and 2.1% changing more than one star
- With the addition of transplant waitlisting measures, facilities that received a higher Star Rating had higher SWR/PPPW measure values on average, and vice versa
- The transplant waitlist measures add new information to the ratings

TEP Discussion

Public Comment Period

2:55 PM, EST

End of Teleconference Call #1

Teleconference Call #2: March 3rd from 1PM – 4PM, EST

Establishing a new baseline for the Star Rating reset and the impact of COVID-19 on reporting and patient outcomes

Teleconference Call #3: March 15th from 1PM – 4PM, EST

Reserved for any outstanding discussion points

Appendix

SWR Data and Exclusions

Minimum Data Requirements: Facilities with at least 11 eligible patients during the calendar year of assessment.

Data Source(s): EQRS, Organ Procurement and Transplant Network (OPTN), Nursing Home Minimum Dataset, CMS Medical Evidence Forms, and Medicare hospice claims data.

Facility Exclusions:

1. Facilities with less than 11 patients or less than 2 expected events for the reporting period.
2. Calculations will exclude the months covered by a granted ECE.

Patient Exclusions:

1. Patients who were 75 years of age or older at the initiation of dialysis
2. Preemptive patients: patients at the facility who had the first transplantation prior to the start of ESRD treatment; or were listed on the kidney or kidney-pancreas transplant waitlist prior to the start of dialysis
3. Patients who were admitted to a hospice at the time of initiation of dialysis
4. Patients who were admitted to an SNF at incidence or previously according to Form CMS-2728

PPPW Data and Exclusions

Minimum Data Requirements: Facilities with at least 11 eligible patients during the calendar year of assessment.

Data Source(s): EQRS, Organ Procurement and Transplant Network (OPTN), Nursing Home Minimum Dataset, CMS Medical Evidence Forms, and Medicare hospice claims data.

Facility Exclusions:

1. Facilities treating fewer than 11 eligible patients during the calendar year of assessment.
2. Calculations will exclude the months covered by a granted ECE.

Patient Exclusions:

1. Patients 75 years old and older on the last day of each month during the performance period.
2. Patients admitted to a skilled nursing facility (SNF) or hospice during the evaluation month are excluded from that month.
3. Patients admitted to SNF at incidence or previously were excluded, according to Question 16u and 21 on the CMS Medical Evidence Form.

Percentage of Prevalent Patients Waitlisted

Additional Information:

1. For each patient, a new record is created each time they change facility or treatment modality.
2. Each record represents a time period associated with a specific modality and dialysis facility.
3. This measure is currently age-adjusted, with age updated each month.
4. The measure is a directly standardized percentage in that each facility's percentage of prevalent patients waitlisted is adjusted to the national age distribution (all facilities combined).

Factor Analysis Results

Estimated correlations (x100) between measures and domains

Measure	Domain 1	Domain 2	Domain 3	Domain 4
STrR	**43**	6	6	13
SHR	**63**	13	5	9
SMR	**26**	4	14	19
SRR	**49**	6	-4	-4
SFR	9	**55**	17	8
LTC	12	**58**	5	16
Hyp.	5	27	-7	**33**
Kt/V	18	29	-13	**36**
SWR	3	5	**53**	-1
PPPW	5	7	**57**	-7

Factor Analysis with Different Domains

In an additional analysis, we checked how the measure domains would look if we chose the number of domains to be 2-5, rather than the suggested number, 4

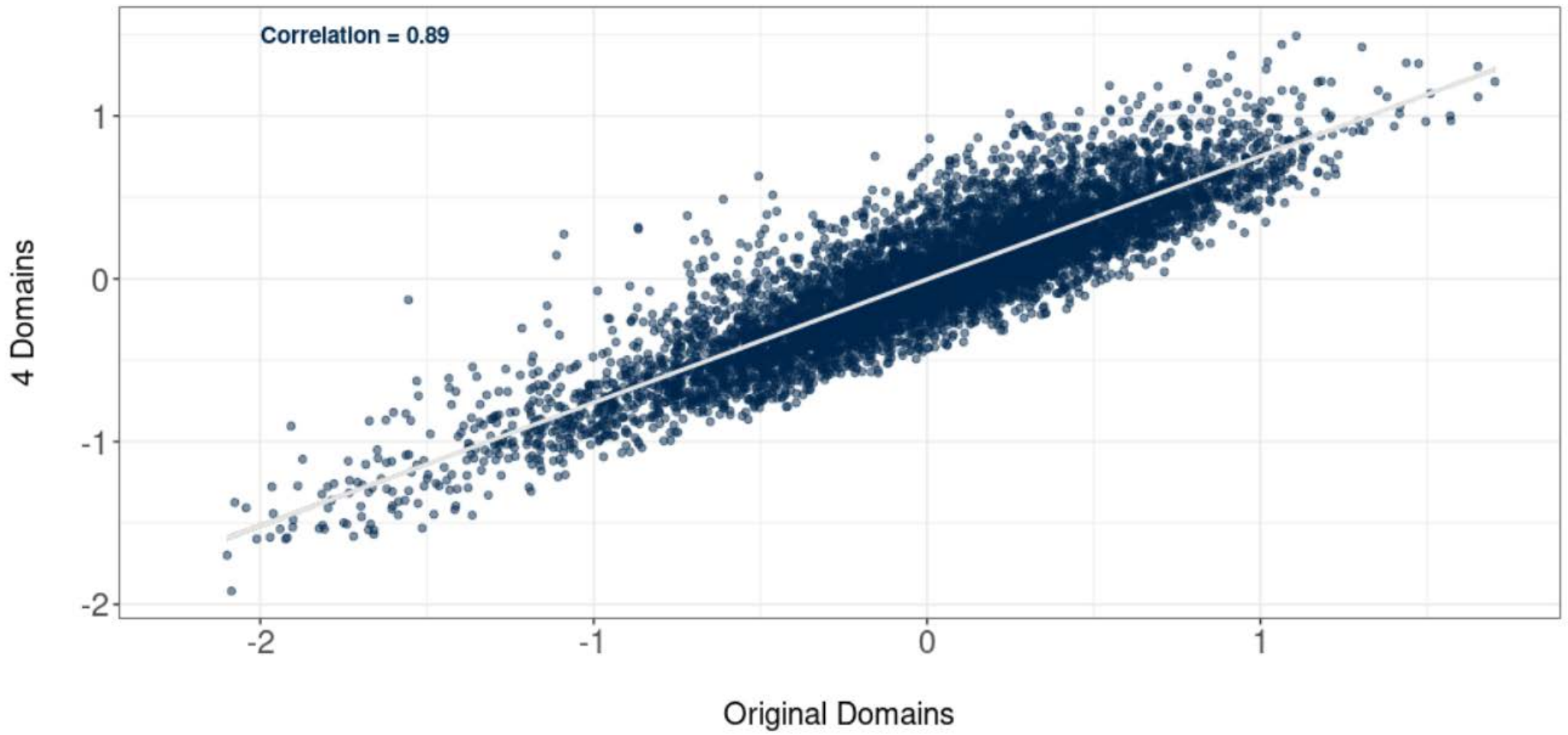
	D1	D2
STrR	**37**	7
SHR	**54**	8
SMR	**27**	13
SRR	**35**	1
SFR	**43**	21
LTC	**50**	9
Hyp.	**33**	-10
Kt/V	**45**	-15
SWR	4	**52**
PPPW	3	**58**

	D1	D2	D3
STrR	10	**44**	5
SHR	15	**63**	4
SMR	11	**28**	11
SRR	4	**48**	-3
SFR	**52**	8	23
LTC	**58**	11	11
Hyp.	**39**	7	-9
Kt/V	**43**	21	-15
SWR	1	5	**52**
PPPW	0	6	**58**

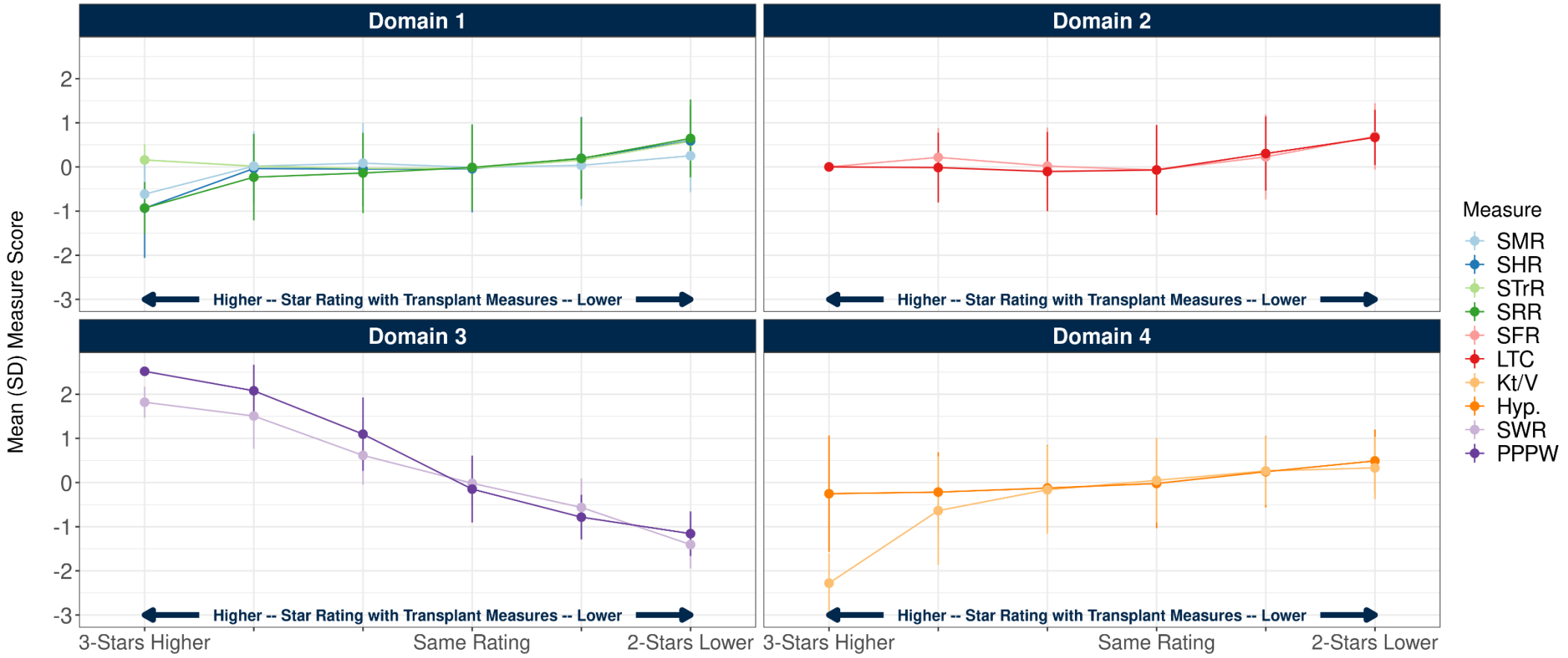
	D1	D2	D3	D4
STrR	**43**	6	6	13
SHR	**63**	13	5	9
SMR	**26**	4	14	19
SRR	**49**	6	-4	-4
SFR	9	**55**	17	8
LTC	12	**58**	5	16
Hyp.	5	27	-7	**33**
Kt/V	18	29	-13	**36**
SWR	3	5	**53**	-1
PPPW	5	7	**57**	-7

	D1	D2	D3	D4	D5
STrR	**43**	6	6	13	2
SHR	**63**	13	5	9	0
SMR	**26**	4	14	19	2
SRR	**49**	6	-4	-4	-2
SFR	9	**55**	17	9	0
LTC	12	**58**	5	16	-1
Hyp.	5	27	-7	**33**	0
Kt/V	18	29	-13	**36**	0
SWR	3	5	**53**	-1	0
PPPW	5	7	**57**	-7	1

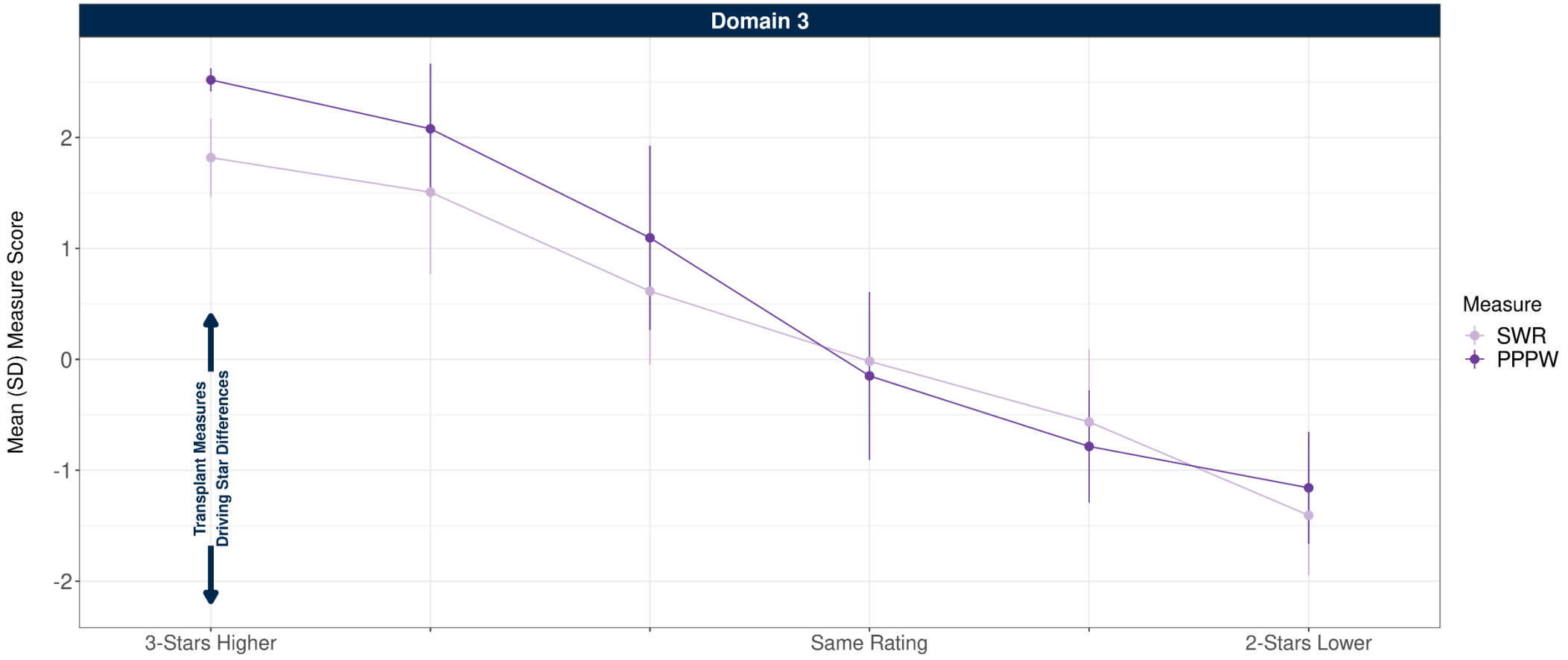
Final Score Agreement



Measure Scores by Star Difference



Impact of Transplant Measures



SCHOOL OF PUBLIC HEALTH
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UNIVERSITY OF MICHIGAN

Dialysis Facility Quality of Patient Care Star Ratings Technical Expert Panel (TEP)

TELECONFERENCE CALL #2

MARCH 3, 2022 · 1PM – 4PM, EST

Discussion Reminders

- Use the ‘raise hand’ function if possible
- Share questions and ideas directly during discussion
- Refrain from using the chat
- Mute yourself when not speaking, unmute when needed
- Public participants may speak at end of the meeting during the allotted public comment period

TEP Meeting #2 Agenda

1:00 PM:	TEP Member, CMS, and UM-KECC Introductions
1:05 PM:	Recap and Continuation of Meeting #1
1:50 PM:	Resetting the Star Ratings and COVID-19 Considerations
2:35 PM:	TEP Discussion and Consensus Recommendation or Vote
3:20 PM:	Public Comment

UM-KECC Star Rating Team

Name and Credentials	Organizational Affiliation	Conflicts of Interest
Yi Li, PhD	Professor, Biostatistics Professor, Global Public Health	None
Joseph Messana, MD	Professor, Internal Medicine, Division of Nephrology Research Professor, Health Management and Policy	None
Claudia Dahlerus, PhD	Assistant Research Scientist, Internal Medicine, Division of Nephrology	None
Richard Hirth, PhD	S. J. Axelrod Collegiate Professor, Health Management and Policy Professor, Internal Medicine	None
Peisong Han, PhD	Associate Professor, Biostatistics	None
Wolf Gremel, MS	Senior Analyst	None

UM-KECC Star Rating Team

Name and Credentials	Organizational Affiliation	Conflicts of Interest
Tao Xu, PhD	Senior Analyst	None
Casey Parrotte, BA, PMP	Continued Improvement Specialist Lead	None
Jennifer Sardone, BA, PMP	Senior Lead Project Manager	None
Eileen Yang, BS	PhD Student, Biostatistics	None
Stephen Salerno, MS	PhD Student, Biostatistics	None
Jaclyn George, AA	Project Manager **Point of Contact:** jaclynrg@umich.edu	None

CMS Representatives

- Golden Horton, MS
- Wilfred Agbenyikey, ScD

TEP Objectives

The 2022 Star Rating TEP is expected to focus on:

1. Providing recommendations on the addition of two transplant waitlist measures
2. Establishing new baseline criteria for updating the Star Rating and discussing the choice of a new baseline year because of COVID-19

TEP Meeting #1 - Recap

- TEP members discussed possible inclusion of up to two transplant waitlist measures in the Star Rating
- A preliminary vote was held to end consideration of either measure (affirmative) versus continuing discussions for either or both measures in the context of additional requested analysis:
  - 7 TEP members voted in the affirmative for ending considerations of either measure
  - 5 TEP members voted for discussion after presentation of additional analysis
  - 1 TEP member was in absentia
- Additional analysis was done to inform the impact on the Star Rating when adding just one measure

Transplant Waitlisting Measures

ADDITIONAL ANALYSIS RESULTS

Factor Analysis Results

We group measures based on their correlations using a statistical approach known as *factor analysis*. Values in the table represent the correlation between the measures and the respective domains.

Just PPPW

	D1	D2	D3
STrR	**44**	14	6
SHR	**63**	11	8
SMR	**29**	3	-1
SRR	**48**	9	5
SFR	20	**45**	-17
LTC	7	**41**	-14
Hyp.	12	**56**	22
Kt/V	9	**49**	32
SWR	-	-	-
PPPW	7	-2	**37**

Just SWR

	D1	D2	D3
STrR	**44**	10	5
SHR	**62**	14	10
SMR	**28**	12	4
SRR	**48**	1	7
SFR	7	**42**	40
LTC	10	**51**	32
Hyp.	7	**42**	-3
Kt/V	10	**46**	-4
SWR	5	-1	**22**
PPPW	-	-	-

PPPW + SWR

	D1	D2	D3	D4
STrR	**43**	6	6	13
SHR	**63**	13	5	9
SMR	**26**	4	14	19
SRR	**49**	6	-4	-4
SFR	9	**55**	17	8
LTC	12	**58**	5	16
Hyp.	5	27	-7	**33**
Kt/V	18	29	-13	**36**
SWR	3	5	**53**	-1
PPPW	5	7	**57**	-7

Star Rating Agreement

Current 3 Domains	4 Domains with SWR + PPPW as a Domain				
	★	★★	★★★	★★★★	★★★★★
★	**7.4%**	2.1%	0.3%	0.1%	-
★★	2.5%	**12.2%**	5.0%	0.2%	-
★★★	-	5.6%	**27.2%**	6.0%	1.1%
★★★★	-	0.1%	7.2%	**9.6%**	3.2%
★★★★★	-	-	0.2%	4.1%	**5.7%**

Star Rating Agreement

Current 3 Domains	4 Domains with SWR as a Standalone Domain				
	★	★★	★★★	★★★★	★★★★★
★	**5.8%**	2.4%	0.7%	-	-
★★	4.0%	**9.7%**	7.4%	0.3%	-
★★★	0.2	7.87%	**24.5%**	8.7%	1.7%
★★★★	-	0.1%	6.88%	**8.6%**	4.2%
★★★★★	-	-	0.5%	2.5%	**4.2%**

Star Rating Agreement

Current 3 Domains	4 Domains with PPPW as a Standalone Domain				
	★	★★	★★★	★★★★	★★★★★
★	**6.9%**	2.1%	0.5%	0.2%	-
★★	3.1%	**10.8%**	5.2%	0.8%	0.1%
★★★	-	7.0%	**24.5%**	6.6%	2.1%
★★★★	-	0.1%	8.7%	**8.1%**	3.3%
★★★★★	-	-	1.0%	4.4%	**4.5%**

Summary of Rating Changes

with the addition of one or both transplant waitlist measures

- 62.2% of facilities received the same rating, and 37.8% changed ratings, comparing the addition of both measures in a separate domain vs. the current domains (κ = 67%)
- 52.8% of facilities received the same rating, and 47.2% changed ratings, comparing the addition of SWR in a standalone domain vs. the current domains (κ = 56%)
- 54.8% of facilities received the same rating, and 45.2% changed ratings, comparing the addition of PPPW in a standalone domain vs. the current domains (κ = 58%)

Summary

- Factor analysis suggests transplant waitlist measures, one or two, form a separate domain of care
- Inclusion of only one waitlist measure causes more changes than inclusion of both, likely because of too much weight put on one single measure

TEP Discussion

Baseline Period for the Star Ratings

CONSIDERATION FOR WHICH BASELINE PERIOD

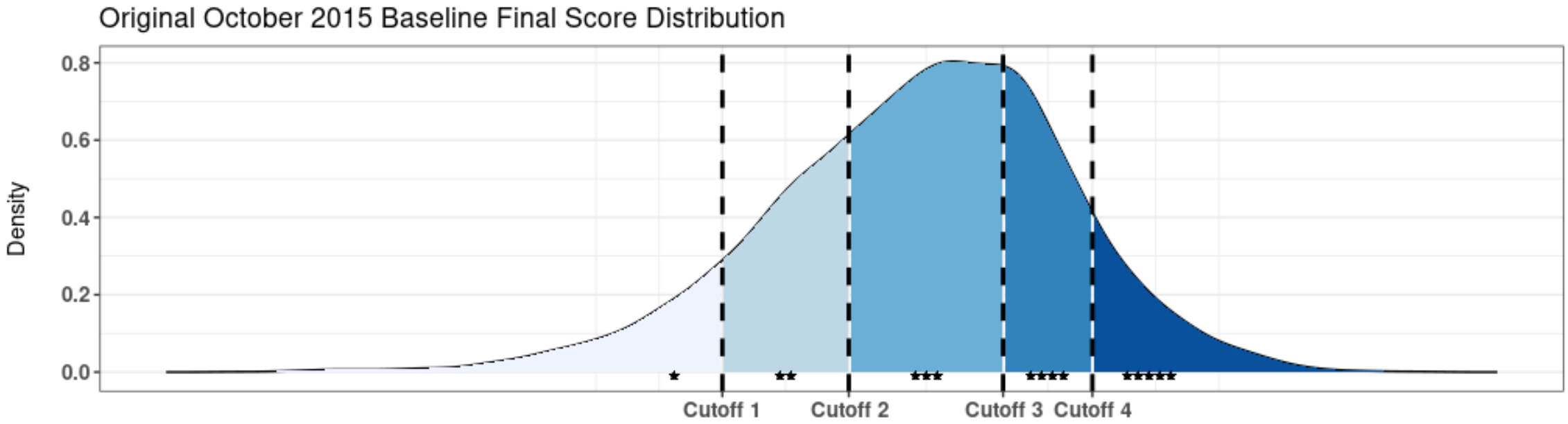
Refresh on 2019 TEP Decisions

1. **Resetting the Star Rating Distribution**
   - Voted to reset the Star Ratings to a 10-20-40-20-10 distribution
   - Establish new baseline star cutoffs based on more current data
2. Re-Weighting Certain Domains of Care
   - Voted to down-weight Domain 3 which contains the Total Kt/V and Hypercalcemia measures
   - Give these measures 50% weight (i.e., half the weight relative to the other domains) moving forward

Resetting the Star Ratings

Resetting: define cutoffs to reset the entire Star Rating distribution

When to Reset: When the Star Rating distribution is significantly compressed, or when the information provided is no longer useful in discriminating facility performance



Considerations for the Star Rating Baseline

1. Timeliness and Proximity to Current Period Reporting

2. ECE Exclusion Period in 2020

3. COVID-19 Prevalence and Impact

Baseline Year Considerations

Baseline Period	COVID-19	Data Reporting	Timeliness
Calendar Year 2019	Data Collected Prior to COVID-19 Pandemic	Complete Data	Least Proximate
Calendar Year 2020	Data Collected During Initial COVID-19 Surges	ECE Exemptions	More Proximate
Calendar Year 2021	First Full Year of Data During COVID-19 Pandemic	Pending	Most Proximate

Additional Considerations?

- COVID-19 effects on supply chain? Staff retention?

Extraordinary Circumstance Exception

Impact of COVID-19

On March 27, 2020, CMS released guidance describing the scope and duration of the Extraordinary Circumstance Exceptions (ECEs) granted under each program:

- Providers were relieved of their obligation to report clinical data Q1 CY 2020, and Q2 CY 2020
- For claims-based measures, claims data from March 1 - June 30, 2020 were excluded from calculations

Impact on Star Rating Measures and Data

Impact of COVID-19 on current and potential Star Rating measures, and the data used to create and adjust them, includes, but is not limited to:

- **Mortality, Hospitalizations, and Readmissions**
- Transfusions
- Transplant Waitlisting
- In-home vs. In-center dialysis
- Kt/V, Hypercalcemia, and Vascular Access Trends
- Population Trends in ESRD

Preliminary Analysis – COVID-19 Impact

- Preliminary analysis on the impact of COVID-19 utilized available claims data from 2020
- Calculated event rates (# events / # at risk) for mortality, hospitalizations, and readmissions – those outcomes most impacted by COVID-19
- Further studied the risk factors for COVID-19 infection and mortality among Medicare dialysis patients in 2020

COVID-19 Prevalence

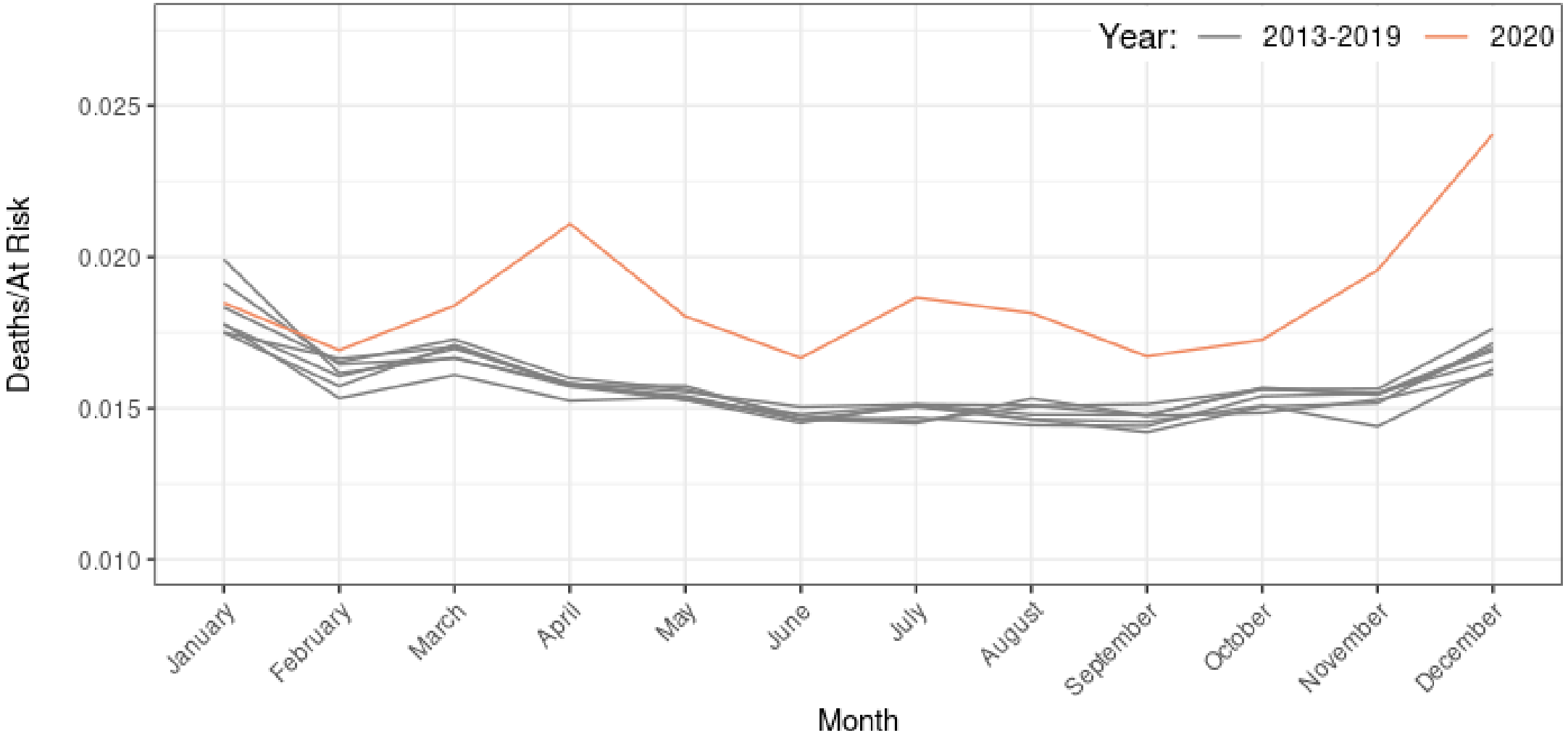
Table 1. COVID-19 patient counts, deaths, and hospitalizations among Medicare dialysis patients, 2020 Q1-Q4

	2020			
Outcome Description	**Jan-Mar**	**Apr-Jun**	**Jul-Sep**	**Oct-Dec**
Medicare dialysis patients (n)	449,718	443,829	441,086	435,765
Patients initially infected with COVID-19 (n)	2,512	17,246	13,590	27,576
% out of all Medicare dialysis patients	0.6	3.9	3.1	6.3
Deaths among Medicare patients				
Deaths (n)	21,913	22,563	21,515	24,277
Deaths among patients initially infected with COVID-19 (n)	298	3,865	2,604	4,798
% out of all deaths	1.4	17.1	12.1	19.8
Hospitalizations[*2] among Medicare patients				
Hospitalizations (n)	137,418	116,868	124,862	126,895
Hospitalizations among patients initially infected with COVID-19 (n)	2,350	13,426	10,594	21,412
% out of all hospitalizations	1.7	11.5	8.5	16.9

[*1] Includes dialysis patients having Medicare as primary insurer or with a Medicare Advantage plan.

[*2] Hospitalization is defined as having at least one day in a hospital from Medicare inpatient claims during the reporting period.

Monthly empirical all-cause mortality hazards (number of deaths/number at risk), among Medicare dialysis patients, from January 1, 2013 to December 31, 2020



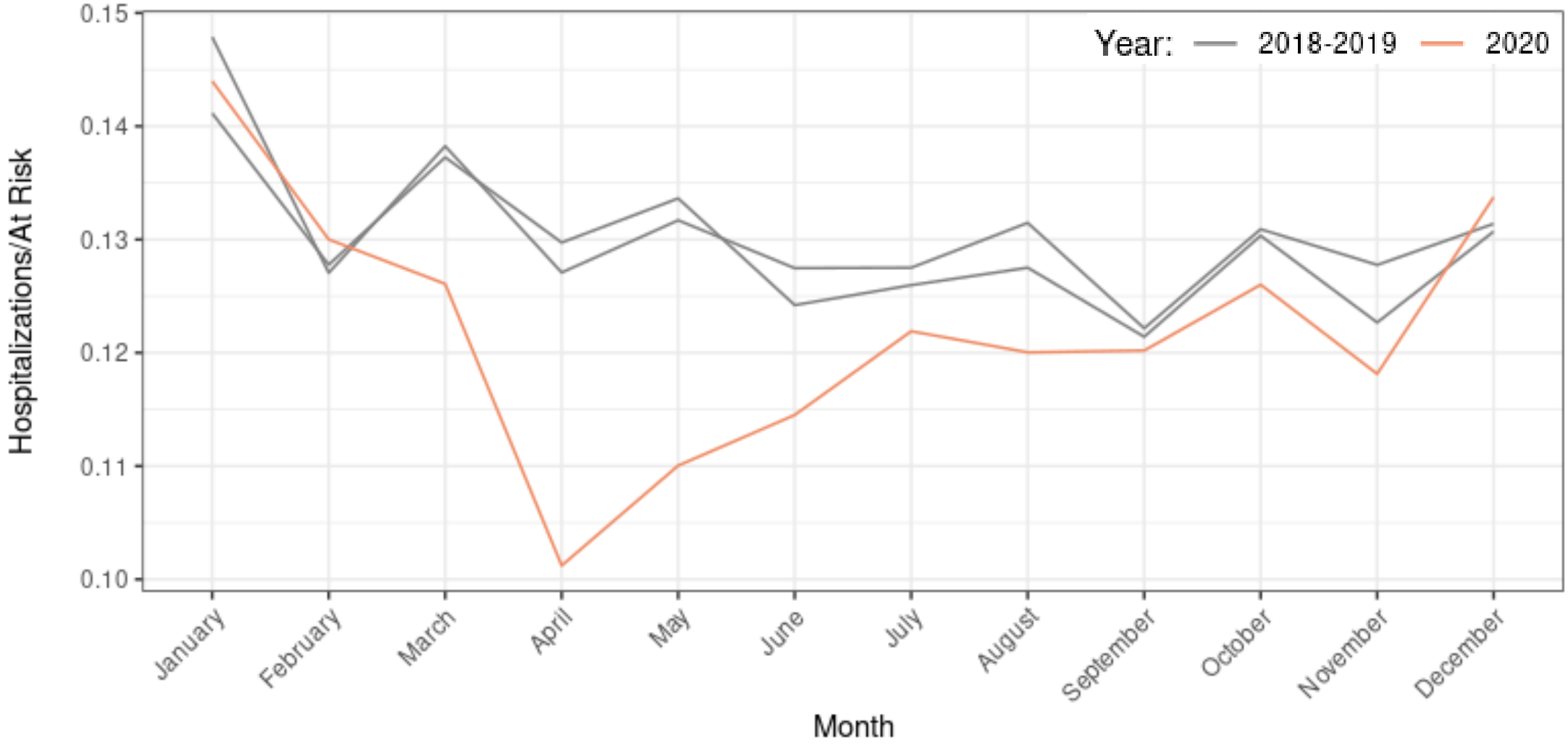
Patient Mortality

All-cause mortality rates among ESRD patients were significantly higher in 2020 than in previous years, with peaks in April, July and December, consistent with known waves of the pandemic in the general population. In addition:

- Risk of COVID-19 was higher among Black and Hispanic patients, patients living in urban areas, and patients in nursing homes
- Existing risk factors for mortality (e.g., older age, male sex, diabetes) were associated with higher post-COVID-19 infection mortality
- Suggests potential interactions between COVID-19 infection and traditional risk factors for mortality

Salerno S, Messana JM, Gremel GW, et al. COVID-19 Risk Factors and Mortality Outcomes Among Medicare Patients Receiving Long-term Dialysis. JAMA Netw Open. 2021;4(11):e2135379.

Monthly empirical all-cause hospitalization hazards (number of admissions/number at risk), among Medicare dialysis patients, from January 1, 2018 to December 31, 2020

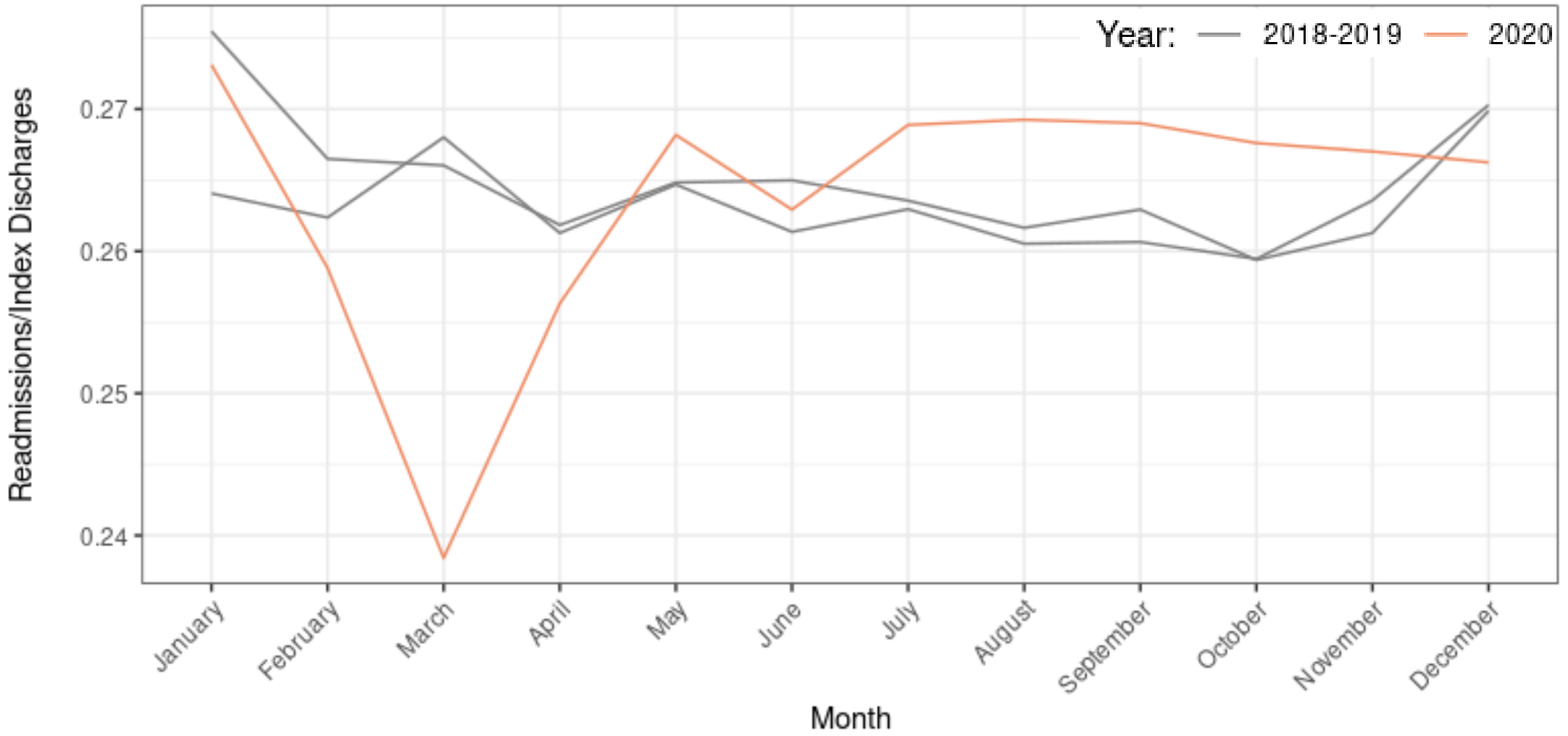


Hospitalization Rates

In 2020, there was a rapid reduction in the hospitalization rate of about 20% beginning in March and then slowly returning to normal levels by July

- This trend differs from 2018 and 2019, despite the expected seasonal decline in the hospitalization rate from January to June
- Suggests a perturbation in hospital use which may have resulted in adverse outcomes among non-COVID patients

Monthly empirical all-cause readmission hazards (number of readmissions/number of index discharges), among Medicare dialysis patients, from Jan. 1, 2018 to Dec. 31, 2020



Readmissions

- Death and 30-day readmissions were initially higher for those with a COVID discharge, but the impact of COVID declines after 7 days post discharge
- Across patient characteristics, often observe lower rates of unadjusted 4-30 day hospital readmission rates following a COVID-19 index hospitalization
- Both the initially higher death rate and observed lower readmission rate among patients with a COVID-19 index discharge suggest potential competing risks of death or discharge to hospice, both of which would remove them from the denominator for SRR

Additional Measures

- After initial decline in spring 2020, no significant changes in transfusion rates were found
- Waitlist removal among prevalent patients (PPPW) and waitlisting and transplants in incident ESRD patients (SWR) declined more significantly in spring 2020 compared to prior seasonal trends, generally returned to normal in June/July 2020
- Compared to 2017-2019, percentage of home dialysis incident patients increased in 2020
- Observed small, but detectable increases in missing values for hypercalcemia and PD Kt/V in March-June 2020, with no change in reporting of HD Kt/V, and no change in patients achieving the calcium or HD Kt/V targets
- There was a notable increase in long-term catheter use and a corresponding decrease in AV fistula use in March, April and May 2020, comparing to the same months in 2019

Baseline Year Considerations

Baseline Period	COVID-19	Data Reporting	Timeliness
Calendar Year 2019	Data Collected Prior to COVID-19 Pandemic	Complete Data	Least Proximate
Calendar Year 2020	Data Collected During Initial COVID-19 Surges	ECE Exemptions	More Proximate
Calendar Year 2021	First Full Year of Data During COVID-19 Pandemic	Pending	Most Proximate

Additional Considerations?

- COVID-19 effects on supply chain? Staff retention?

Questions

ANY QUESTIONS FROM THE TEP ON THE IMPACT OF COVID-19?

TEP Discussion

Public Comment Period

2:55 PM, EST

End of Teleconference Call #2

Teleconference Call #3: March 15th from 1PM – 4PM, EST

Reserved for any outstanding discussion points

Appendix

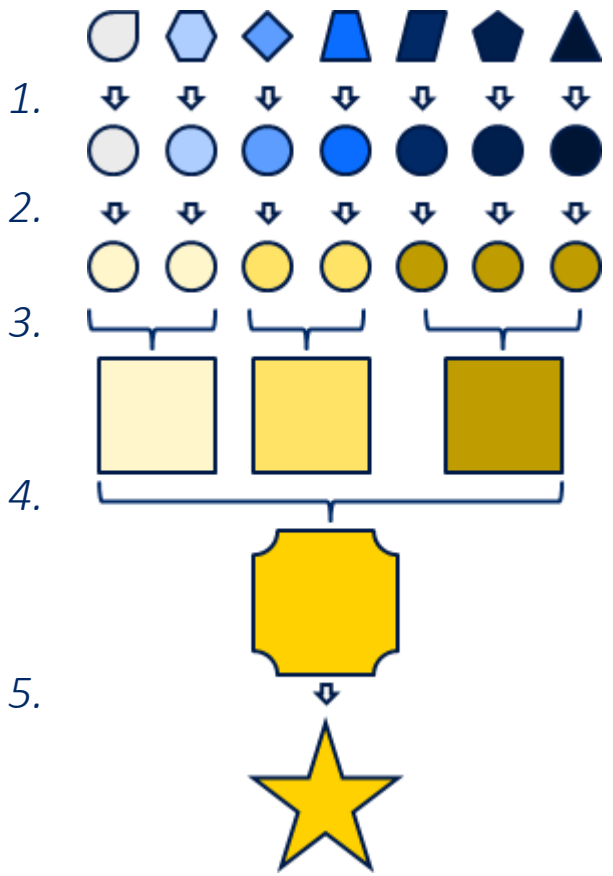
Star Ratings

Key Concepts and Terminology

Term	Definition
Measure Value	The original value of a facility's clinical quality measure as reported on DFC, which represents a ratio or a percentage
Measure Score	A standardized score applied to a specific measure, so that no measure has undue influence on the Star Ratings, and so that the range and direction of scores are consistent (mean 0, variance 1)
Domain Score	A score which summarizes a facility's performance on a group of correlated clinical quality measures. It is an average of the individual measure scores in that group (domain)
Final Score	A continuous score calculated for each facility, which summarizes its performance on the reported clinical quality measures. It is an average of the three domain scores
Cutoff	A value of the final score that defines the boundary between two adjacent Star Rating categories (e.g., the cutoff between 4- and 5-stars is 1.36 and facilities with a final score > 1.36 receive 5 stars)

Star Rating Overview

1. *Measure values* on different scales are standardized against a *baseline period* to form *measure scores* with the same interpretation
2. *Individual measures* are grouped into different measure domains based on their correlations
3. *Measure scores* within a domain are averaged to form *domain scores*
4. *Domain scores* are averaged to form a *final score* for each facility
5. *Final scores* are grouped into five star categories based on pre-established Star Rating *cutoff* values



Key Concepts and Terminology

Term	Definition
Baseline Period	The time period (e.g., calendar year) in which data are collected for computing measure scoring criteria and defining cutoff values for Star Rating categories. The cutoffs will be used to rate facilities in future evaluation periods
Evaluation Period	The time period (e.g., calendar year) in which data are collected for calculation of measure results and facility Star Rating scores, reported on DFC. Final scores in the evaluation period are compared against cutoffs established in the baseline period in order to rate facilities
Rebaselining	Establish a new baseline period and scoring cutoffs. These cutoffs let the Star Rating distribution remain unchanged from the past release to allow for continuity over time when updating measures
Resetting	Establish a new baseline period, scoring cutoffs, and Star Rating distribution. These cutoffs define a new Star Rating distribution to better differentiate facility performance

Current Star Rating Measures

Domain	Measure
1	Standardized Transfusion Ratio for Dialysis Facilities (STrR)
	Standardized Mortality Ratio for Dialysis Facilities (SMR)
	Standardized Hospitalization Ratio for Dialysis Facilities (SHR)
	Standardized Readmission Ratio for Dialysis Facilities (SRR)
2	Hemodialysis Vascular Access: Standardized Fistula Rate (SFR)
	Hemodialysis Vascular Access: Long-Term Catheter Rate (LTC)
3	Total Kt/V (Kt/V)*
	Proportion of Patients with Hypercalcemia (Hyp.)

**Four Kt/V measurements (adult/pediatric, HD/PD) are combined into a single, Total Kt/V measure*

Shifting Star Rating Distribution

Transplant Waitlist Measures

SWR + PPPW versus Current Ratings

We examined the relationships between SWR and PPPW values versus the Star Ratings without transplant measures:

- a weak trend with higher average performance values for SWR and PPPW among facilities with higher Star Ratings

Mean (SD) Measure Value by Star Rating under Current Domains

Measure	1-Star	2-Stars	3-Stars	4-Stars	5-Stars
SWR	0.85 (0.76)	0.84 (0.71)	1.00 (0.80)	1.06 (0.82)	1.16 (0.89)
PPPW	15.70 (10.73)	16.05 (9.65)	18.16 (10.12)	18.68 (10.57)	18.60 (10.76)

COVID-19 Impact

Preliminary Medicare COVID-19 Data Snapshot:

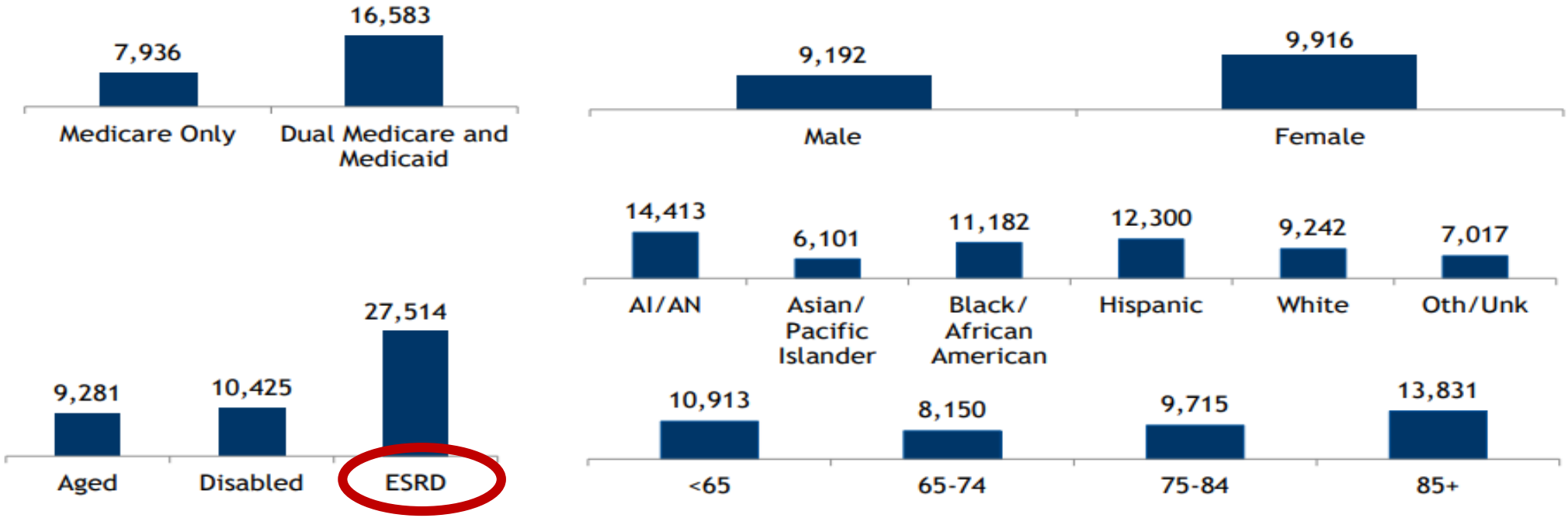
Medicare Claims and Encounter Data: January 1, 2020 to November 20, 2021, Received by December 17, 2021

COVID-19 Cases

6,065,548 Total COVID-19 Cases

9,587 COVID-19 Cases per 100k

COVID-19 Cases per 100K by Beneficiary Characteristics



Note: AI/AN = American Indian/Alaska Native

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Preliminary Medicare COVID-19 Data Snapshot:

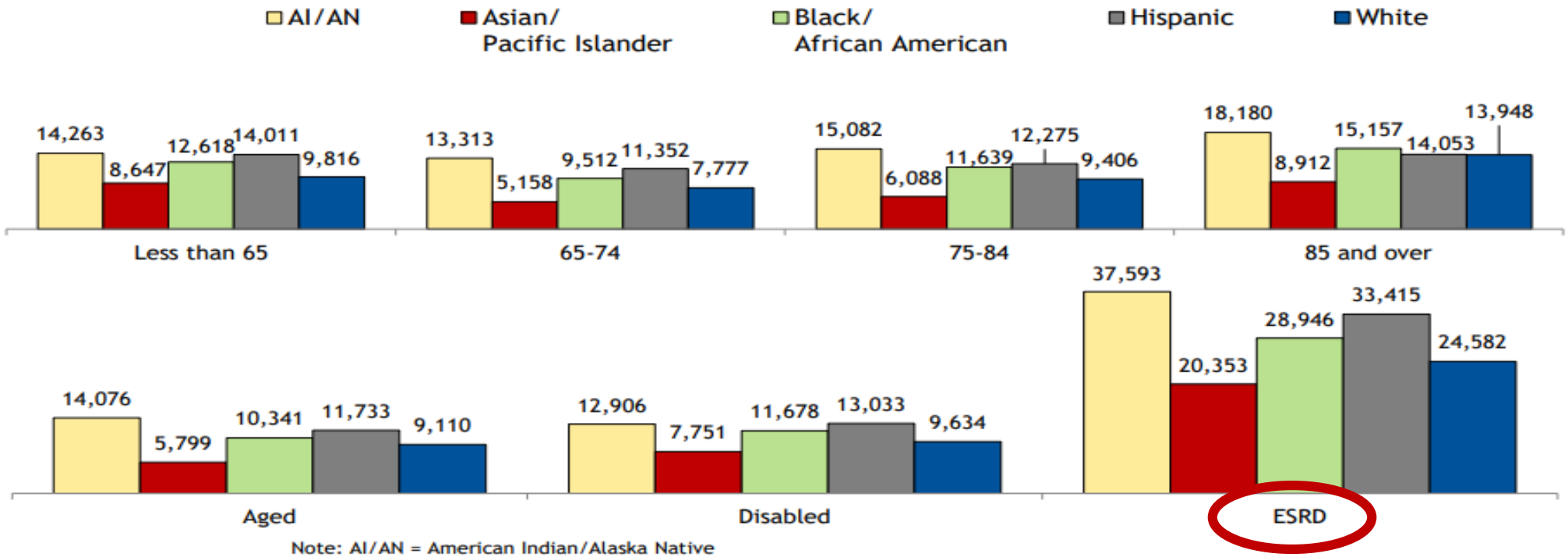
Medicare Claims and Encounter Data: January 1, 2020 to November 20, 2021, Received by December 17, 2021

COVID-19 Cases

6,065,548 Total COVID-19 Cases **9,587** COVID-19 Cases per 100k

COVID-19 Cases per 100K by Beneficiary Characteristics

- By Race/Ethnicity -



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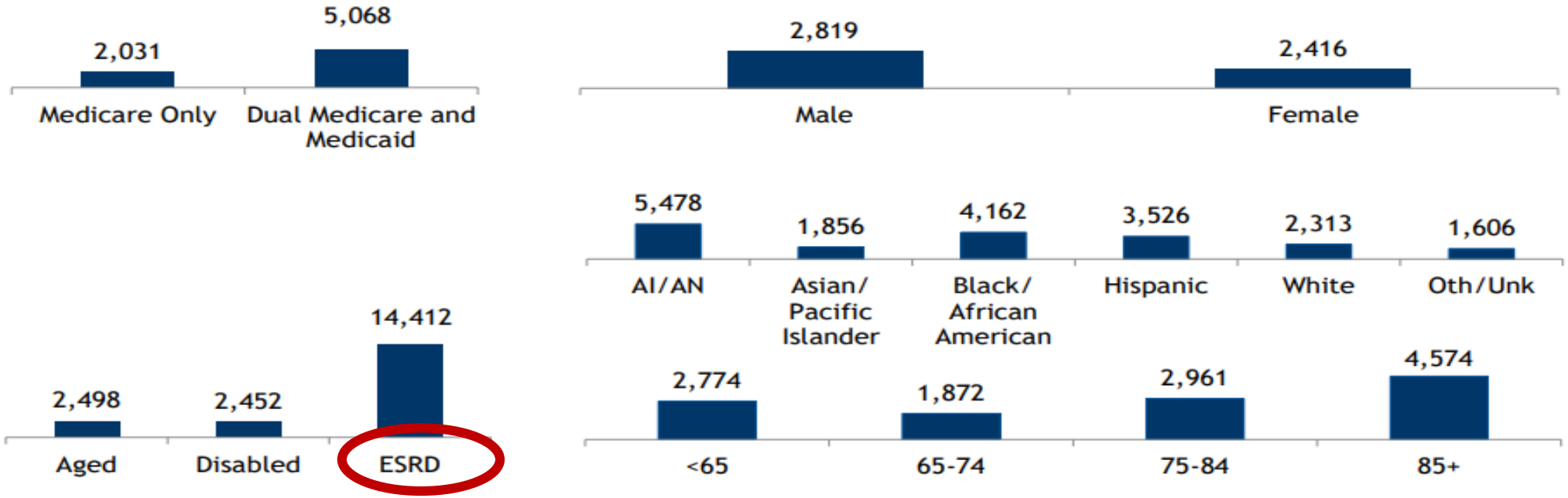
Preliminary Medicare COVID-19 Data Snapshot:

Medicare Claims and Encounter Data: January 1, 2020 to November 20, 2021, Received by December 17, 2021

COVID-19 Hospitalizations

1,636,501 Total COVID-19 Hospitalizations **2,600** COVID-19 Hospitalizations per 100k

COVID-19 Hospitalizations per 100K by Beneficiary Characteristics



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Preliminary Medicare COVID-19 Data Snapshot:

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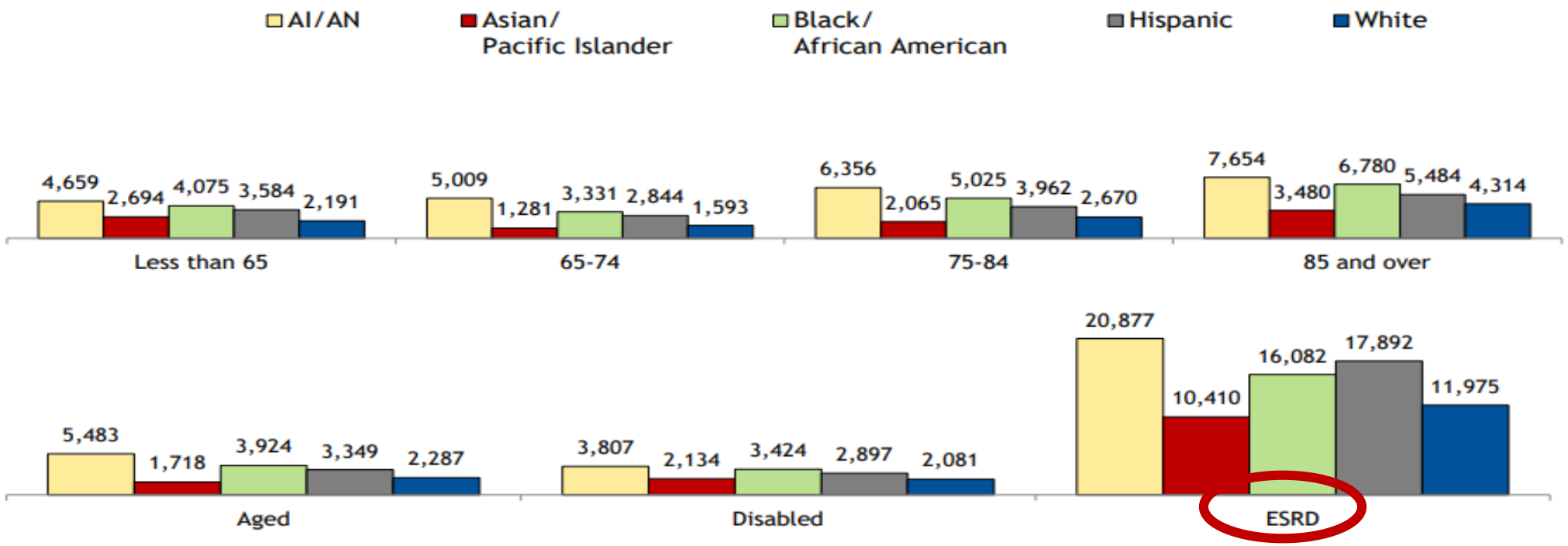
COVID-19 Hospitalizations

1,636,501 Total COVID-19 Hospitalizations **2,600** COVID-19 Hospitalizations per 100k

COVID-19 Hospitalizations per 100K by Beneficiary Characteristics

- By Race/Ethnicity -



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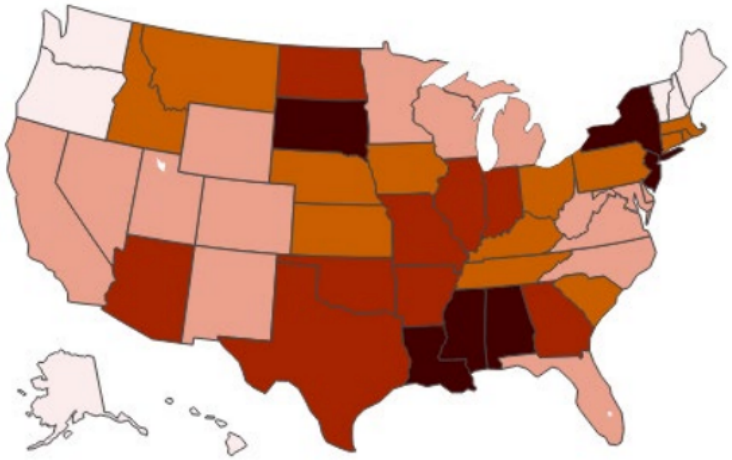
Preliminary Medicare COVID-19 Data Snapshot:

Medicare Claims and Encounter Data: January 1, 2020 to February 20, 2021, Received by March 19, 2021

COVID-19 Cases

3,860,957 Total COVID-19 Cases **6,144** COVID-19 Cases per 100k

COVID-19 Cases per 100K by Geography



Rural Areas: **6,414** per 100K

Urban Areas: **6,138** per 100K

Map Scale: per 100K

1,105 – 3,415	3,416 – 5,594	5,595 – 6,771	6,772 – 7,803	7,804 – 9,355

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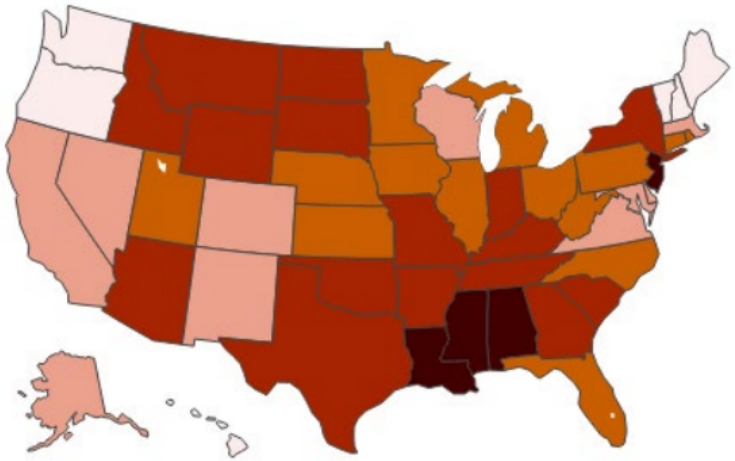
Preliminary Medicare COVID-19 Data Snapshot:

Medicare Claims and Encounter Data: January 1, 2020 to November 20, 2021, Received by December 17, 2021

COVID-19 Cases

6,065,548 Total COVID-19 Cases **9,587** COVID-19 Cases per 100k

COVID-19 Cases per 100K by Geography



Rural Areas: **10,597** per 100K

Urban Areas: **9,437** per 100K

Map Scale: per 100K

2,512 – 5,653	5,654 – 8,368	8,369 – 9,830	9,831 – 12,084	12,085 – 14,734

Note: We are unable to assign Rural/Urban status for around 1% of Medicare enrollees. This may result in a national COVID-19 case rate that is lower than both the Rural and Urban rates displayed above.

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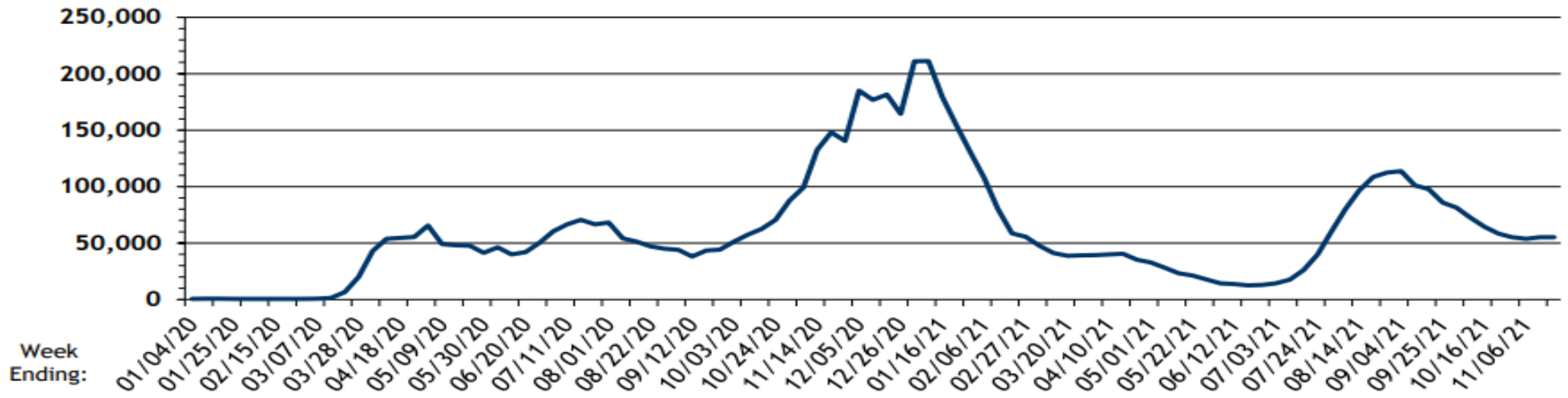
Medicare Claims and Encounter Data: January 1, 2020 to November 20, 2021, Received by December 17, 2021

COVID-19 Cases

6,065,548 Total COVID-19 Cases

9,587 COVID-19 Cases per 100k

COVID-19 Case Trend



Note: Data for recent weeks is likely to be adjusted upward due to claims lag; see page 2 of this data update for additional details on claims lag. For data on COVID-19 vaccinations, visit the CDC COVID-19 Data Tracker here: https://covid.cdc.gov/covid-data-tracker/#vaccinations.

CMS CENTERS FOR MEDICARE & MEDICAID SERVICES

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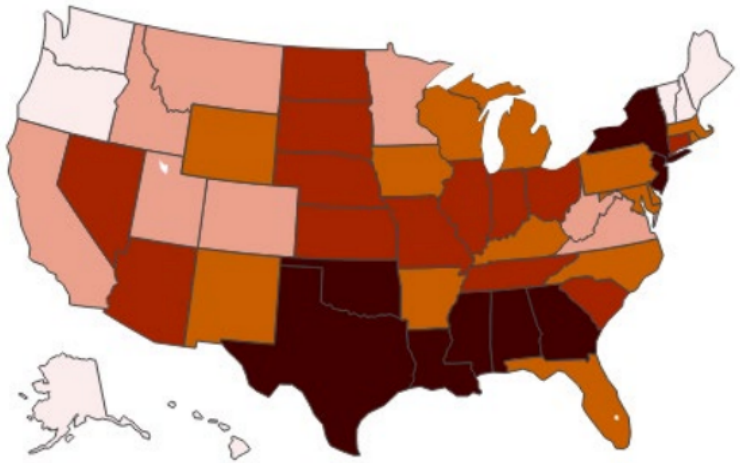
Preliminary Medicare COVID-19 Data Snapshot:

Medicare Claims and Encounter Data: January 1, 2020 to February 20, 2021, Received by March 19, 2021

COVID-19 Hospitalizations

1,058,736 Total COVID-19 Hospitalizations **1,694** COVID-19 Hospitalizations per 100k

COVID-19 Hospitalizations per 100K by Geography



Rural Areas: **1,696** per 100K

Urban Areas: **1,710** per 100K

Map Scale: per 100K

277 – 824	825 – 1,386	1,387 – 1,726	1,727 – 2,083	2,084 – 2,551

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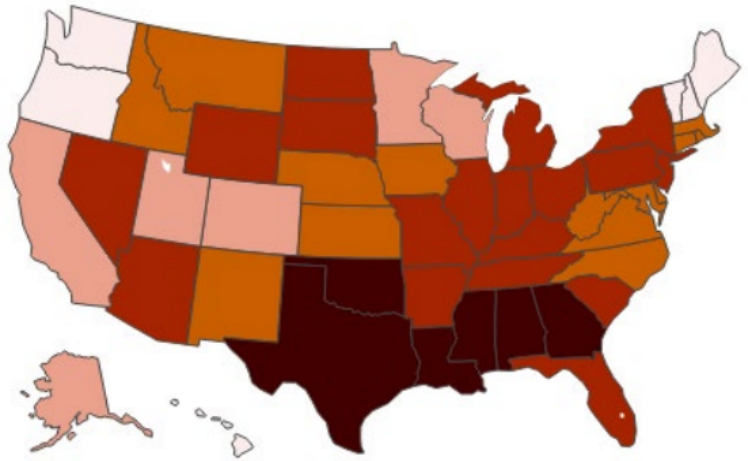
COVID-19 Hospitalizations

1,636,501 Total COVID-19 Hospitalizations **2,600** COVID-19 Hospitalizations per 100k

COVID-19 Hospitalizations per 100K by Geography



Rural Areas: **2,698** per 100K

Urban Areas: **2,602** per 100K

Map Scale: per 100K

548 – 1,322	1,323 – 2,121	2,122 – 2,556	2,557 – 3,096	3,097 – 3,706

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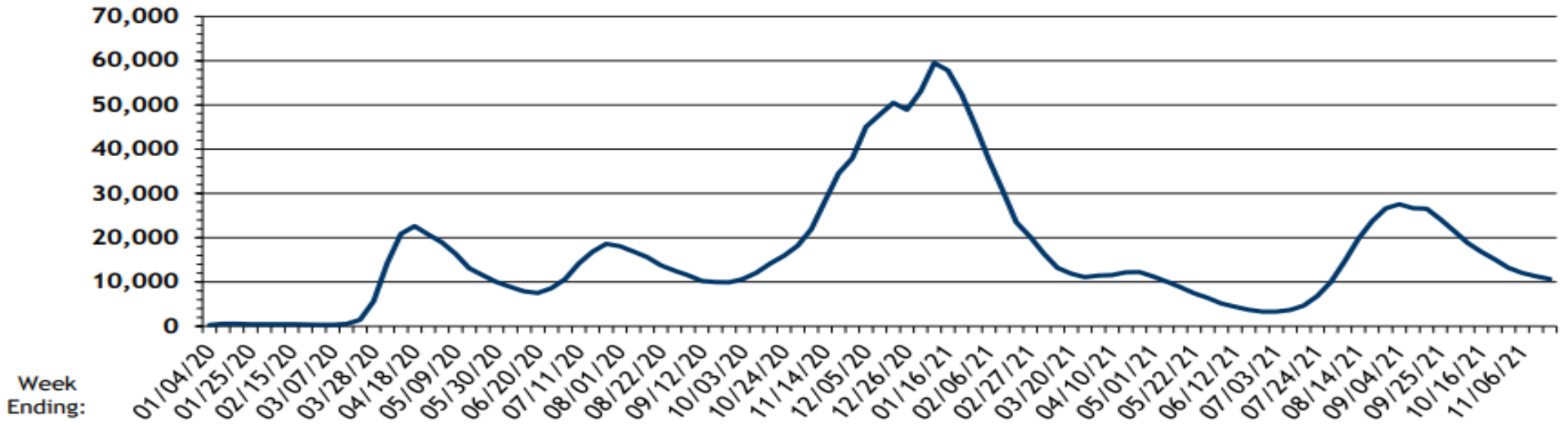
COVID-19 Hospitalizations Trend



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