Measure Justification Form and Instructions

Project Title: ***Practitioner Level Measurement of Effective Access to Kidney Transplantation.***

Date:

Information included is current on *February 9, 2022*.

Project Overview:

The Centers for Medicare & Medicaid Services (CMS) has the University of Michigan Kidney Epidemiology and Cost Center (UM-KECC) to develop practitioner-level measures in the area of access to kidney transplantation for dialysis patients. The contract name is Kidney Disease Quality Measure Development, Maintenance, and Support. The contract number is 75FCMC18D0041, task order number 75FCMC18F0001.

Measure Name/Title (NQF Measure Submission Form sp.01)

First Year Standardized Waitlist Ratio (FYSWR).

1. Type of Measure

☐process
☐process: appropriate use
☒outcome
☐cost/resource use
☐experience with care
☐efficiency
☐outcome: PRO/PRO-PM
☐structure
☐outcome: intermediate outcome
☐composite

2. Importance (NQF Importance to Measure and Report)

2.1 Evidence to Support the Measure Focus (for reference only) NQF Measure evaluation criterion 1a.

2.1.1 This is a Measure of

☐process:
☐process: appropriate use:
☒outcome: *new placement on the kidney or kidney-pancreas transplantation waitlist or receipt of a living donor transplant within the first year after dialysis initiation, with the intended objective of improving the overall health of patients on dialysis*
☐outcome: PRO:

☐cost/resource use:
☐experience with care:
☐efficiency:
☐structure:
☐intermediate outcome:
☐composite:

2.1.2 Logic Model (NQF Measure Submission Form, Importance to Measure and Report: Evidence 1a.01)

This measure tracks the outcomes of new placement on the kidney or kidney-pancreas transplantation waitlist or receipt of a living donor transplant within the first year after dialysis initiation, with the intended objective of improving the overall health of patients on dialysis. Being waitlisted or receiving a living donor kidney transplant are outcomes as they represent a desirable change in health status for patients on dialysis, indicating achievement of a health condition conducive to kidney transplantation. These outcomes result from specific activities directed by dialysis practitioners with the particular goal of achieving suitability for kidney transplantation by addressing the specific healthcare needs of patients on dialysis. These activities can include, but are not limited to, ensuring an ideal dialysis prescription and care, correction and optimization of common underlying chronic health conditions such as heart failure, coronary artery disease, diabetes mellitus, hyperparathyroidism, and obesity, and as needed, optimizing mental health and social support systems. In addition, dialysis practitioners support the path for patients towards waitlisting or living donor transplantation through proper education about the transplantation option, referral to a transplant center and assistance with completion of the transplant evaluation process. The logic model for the steps involved is diagrammed below (with the outcome measure in bold):

Patients with ESRD are initiated on dialysis -> Patients not already on the wait list are educated about the option of kidney transplantation and assessed for eligibility for transplant referral by a dialysis practitioner -> Patients are referred to a transplant center for evaluation of candidacy for kidney or kidney-pancreas transplantation -> Dialysis practitioners assist patient with completion of the transplant evaluation process and optimizing their health and functional status -> ***Patients deemed to be candidates for transplantation who have compatible living donors receive living donor transplant; otherwise they are placed on the wait list with the potential to receive a deceased donor transplant.***

2.1.3 Value and Meaningfulness (NQF Measure Submission Form, Importance to Measure and Report: Evidence [Outcomes] 1a.02)

2.1.4 Empirical Data (for outcome measures) – as applicable (NQF Measure Submission Form, Importance to Measure and Report: Evidence [Outcomes] 1a.03)

Two previous Technical Expert Panels (TEP) have been convened to discuss potential measures directed at improving access to kidney transplantation, in 2015 and most recently, in 2021 (2015 TEP Report: https://dialysisdata.org/sites/default/files/content/ESRD_Measures/Access_To_Kidney_Transplantation_TEP_Summary_Report.pdf; 2021 TEP Report: https://dialysisdata.org/content/esrd-measures, please see Practitioner Level Measurement of Effective Access to Kidney Transplantation under Ongoing Technical Expert Panels section). Both were comprised of relevant stakeholders, including dialysis nephrologists, transplant nephrologists, transplant surgeons, social workers, researchers, and notably, patient representatives with a history of end-stage kidney disease. Discussions during both TEPs revealed broad support for the importance of waitlisting, and formal voting demonstrated a majority of TEP *members were in favor of the development of quality measures targeting waitlisting (at the dialysis facility level for the 2015 TEP, and the practitioner level for the 2021 TEP).*

In addition to the above, empirical support for the value of waitlisting to patients comes from a published study reporting on a large survey of 409 patients or family members who agreed to receiving emails from the National Kidney Foundation (Husain S.A. et al, Am. J. Transplant 2018;18(11):2781-2790). Participants included both patients with advanced chronic kidney disease prior to transplant, and recipients of transplants, who were asked about their priorities in choice of a transplant center. Notably, participants were most likely (a plurality of participants) to rank waitlisting characteristics (such as ease of getting on the waitlist) as the most important feature, in contrast to other transplant center characteristics such as post-transplant outcomes and practical considerations (e.g. distance to center).

National or large regional studies provide strong empirical support for the association between processes under dialysis practitioner control and subsequent waitlisting. In one large regional study conducted on facilities in the state of Georgia, a standardized dialysis facility referral ratio was developed, adjusted for age, demographics and comorbidities (Paul S. et al, Clin J Am Soc Nephrol 2018;13:282-289). There was substantial variability across dialysis facilities in referral rates, and a Spearman correlation performed between ranking on the referral ratio and dialysis facility waitlist rates was highly significant ($r=0.35$, $p<0.001$). A national study using registry data (United States Renal Data System) from 2005-2007 examined the association between whether patients were informed about kidney transplantation (based on reporting on the Medical Evidence Form 2728) and subsequent access to kidney transplantation (waitlisting or receipt of a live donor transplant) (Kucirka LM et al. Am J Transplant 2012;12:351-357). Approximately 30% of patients were uninformed about kidney transplantation, and this was associated with half the rate of access to transplantation compared to patients who were informed. In a related survey study of 388 hemodialysis patients, whether provision of information about transplantation by nephrologists or dialysis staff occurred was directly confirmed with patients (Salter ML et al, J Am Soc Nephrol 2014;25:2871-2877). Patient report of provision of such information was associated with a three-fold increase in likelihood of waitlisting. Finally, a large survey study of 170 dialysis facilities in the Heartland Kidney Network (Iowa, Kansas, Missouri and Nebraska) was conducted to examine transplant education practices (Waterman AD et al, Clin J Am Soc Nephrol 2015;10:1617-1625). Facilities employing multiple (>3) transplant education strategies (e.g. provision of brochures, referral to formal transplant education program, distribution of transplant center contact information) had 36% higher waitlist rates compared to facilities employing fewer strategies.

2.1.5 Systematic Review of the Evidence (for intermediate outcome, process, or structure quality measures, include those that are instrument-based) – as applicable (Measure Submission Form, Importance to Measure and Report: Evidence [Process] 1a.02)

N/A

2.1.6 Other Source of Evidence – as applicable (NQF Measure Submission Form, Importance to Measure and Report: Evidence [Process] 1a.13)

N/A

2.1.6.1 Briefly Synthesize the Evidence (NQF Measure Submission Form, Importance to Measure and Report: Evidence [Process] 1a.14)

N/A

2.1.6.2 Process Used to Identify the Evidence (NQF Measure Submission Form, Importance to Measure and Report: Evidence [Process] 1a.15)

N/A

2.1.6.3 Citation(s) for the Evidence (NQF Measure Submission Form, Importance to Measure and Report: Evidence [Process] 1a.16)

N/A

2.2 Performance Gap – Opportunity for Improvement (NQF Measure evaluation criterion 1b)

2.2.1 Rationale (NQF Measure Submission Form, Importance to Measure and Report: Gap in Care/Disparities 1b.01)

A measure focusing on the outcome of waitlisting is appropriate for several reasons. First, in preparing patients for suitability for waitlisting, dialysis practitioners optimize their health and functional status, improving their overall health state. Second, waitlisting is a necessary step prior to potential receipt of a deceased donor kidney transplant (receipt of a living donor kidney is also accounted for in the measure), which is known to be beneficial for survival and quality of life [1]. Third, dialysis practitioners exert substantial control over the processes that result in waitlisting. This includes proper education of dialysis patients on the option for transplant, referral of appropriate patients to a transplant center for evaluation, and assisting patients with completion of the transplant evaluation process, in order to increase their candidacy for transplant waitlisting. These types of activities are included as part of the conditions for coverage for Medicare certification of ESRD dialysis facilities. Finally, wide regional and facility variations in waitlisting rates highlight substantial room for improvement for this measure [2-5].

Additionally, this measure focuses specifically on the population of patients incident to dialysis, examining for waitlist or living donor transplant events occurring within a year of dialysis initiation. This will evaluate and encourage rapid attention from dialysis practitioner groups to the optimization of health of patients to ensure early access to the waitlist, which has been demonstrated to be particularly beneficial [6-9]. This measure contrasts with the other proposed waitlisting measures, which focus on a prevalent population of dialysis patients and encourage maintenance of patients on the waitlist (Percent of Prevalent Patients Waitlisted and Percent of Prevalent Patients Waitlisted in Active Status).

1. Tonelli M, Wiebe N, Knoll G, et al. Systematic review: kidney transplantation compared with dialysis in clinically relevant outcomes. American Journal of Transplantation 2011;11:2093-2109.

Abstract: Individual studies indicate that kidney transplantation is associated with lower mortality and improved quality of life compared with chronic dialysis treatment. We did a systematic review to summarize the benefits of transplantation, aiming to identify characteristics associated with especially large or small relative benefit. Results were not pooled because of expected diversity inherent to observational studies. Risk of bias was assessed using the Downs and Black checklist and items related to time-to-event analysis techniques. MEDLINE and EMBASE were searched up to February 2010. Cohort studies comparing adult chronic dialysis patients with kidney transplantation recipients for clinical outcomes were selected. We identified 110 eligible studies with a total of 1 922 300 participants. Most studies found significantly lower mortality associated with transplantation, and the relative magnitude of the benefit seemed to increase over time ($p < 0.001$). Most studies also found that the risk of cardiovascular events was significantly reduced among transplant recipients. Quality of life was significantly and substantially better among transplant recipients. Despite increases in the age and *comorbidity of contemporary transplant recipients, the relative benefits of transplantation seem to be increasing over time. These findings validate current attempts to increase the number of people worldwide that benefit from kidney transplantation.*

2. Ashby VB, Kalbfleisch JD, Wolfe RA, et al. Geographic variability in access to primary kidney transplantation in the United States, 1996-2005. American Journal of Transplantation 2007; 7 (5 Part 2):1412-1423.

Abstract: This article focuses on geographic variability in patient access to kidney transplantation in the United States. It examines geographic differences and trends in access rates to kidney transplantation, in the component rates of wait-listing, and of living and deceased donor transplantation. Using data from Centers for Medicare and Medicaid Services and the Organ Procurement and Transplantation Network/Scientific Registry of Transplant Recipients, we studied 700,000+ patients under 75, who began chronic dialysis treatment, received their first living donor kidney transplant, or were placed on the waiting list pre-emptively. Relative rates of wait-listing and transplantation by State were calculated using Cox regression models, adjusted for patient demographics. There were geographic differences in access to the kidney waiting list and to a kidney transplant. Adjusted wait-list rates ranged from 37% lower to 64% higher than the national average. The living donor rate ranged from 57% lower to 166% higher, while the deceased donor transplant rate ranged from 60% lower to 150% higher than the national average. In general, States with higher wait-listing rates tended to have lower transplantation rates and States with lower wait-listing rates had higher transplant rates. Six States demonstrated both high wait-listing and deceased donor transplantation rates while six others, plus D.C. and Puerto Rico, were below the national average for both parameters.

3. Satayathum S, Pisoni RL, McCullough KP, et al. Kidney transplantation and wait-listing rates from the international Dialysis Outcomes and Practice Patterns Study (DOPPS). Kidney Intl 2005 Jul; 68 (1):330-337.

Abstract: BACKGROUND: The international Dialysis Outcomes and Practice Patterns Study (DOPPS I and II) allows description of variations in kidney transplantation and wait-listing from nationally representative samples of 18- to 65-year-old hemodialysis patients. The present study examines the health status and socioeconomic characteristics of United States patients, the role of for-profit versus not-for-profit status of dialysis facilities, and the likelihood of transplant wait-listing and transplantation rates.

METHODS: Analyses of transplantation rates were based on 5267 randomly selected DOPPS I patients in dialysis units in the United States, Europe, and Japan who received chronic hemodialysis therapy for at least 90 days in 2000. Left-truncated Cox regression was used to assess time to kidney transplantation. Logistic regression determined the odds of being transplant wait-listed for a cross-section of 1323 hemodialysis patients in the United States in 2000. Furthermore, kidney transplant wait-listing was determined in 12 countries from cross-sectional samples of DOPPS II hemodialysis patients in 2002 to 2003 (N= 4274).

RESULTS: Transplantation rates varied widely, from very low in Japan to 25-fold higher in the United States and 75-fold higher in Spain (both P values <0.0001). Factors associated with higher rates of transplantation included younger age, nonblack race, less comorbidity, fewer years on dialysis, higher income, and higher education levels. The likelihood of being wait-listed showed wide variation *internationally and by United States region but not by for-profit dialysis unit status within the United States.*

CONCLUSION: DOPPS I and II confirmed large variations in kidney transplantation rates by country, even after adjusting for differences in case mix. Facility size and, in the United States, profit status, were not associated with varying transplantation rates. International results consistently showed higher transplantation rates for younger, healthier, better-educated, and higher income patients.

4. Patzer RE, Plantinga L, Krisher J, Pastan SO. Dialysis facility and network factors associated with low kidney transplantation rates among United States dialysis facilities. Am J Transplant. 2014 Jul; 14(7):1562-72.

Abstract: Variability in transplant rates between different dialysis units has been noted, yet little is known about facility-level factors associated with low standardized transplant ratios (STRs) across the United States End-stage Renal Disease (ESRD) Network regions. We analyzed Centers for Medicare & Medicaid Services Dialysis Facility Report data from 2007 to 2010 to examine facility-level factors associated with low STRs using multivariable mixed models. Among 4098 dialysis facilities treating 305 698 patients, there was wide variability in facility-level STRs across the 18 ESRD Networks. Four-year average STRs ranged from 0.69 (95% confidence interval [CI]: 0.64-0.73) in Network 6 (Southeastern Kidney Council) to 1.61 (95% CI: 1.47-1.76) in Network 1 (New England). Factors significantly associated with a lower STR ($p<0.0001$) included for-profit status, facilities with higher percentage black patients, patients with no health insurance and patients with diabetes. A greater number of facility staff, more transplant centers per 10,000 ESRD patients and a higher percentage of patients who were employed or utilized peritoneal dialysis were associated with higher STRs. The lowest performing dialysis facilities were in the Southeastern United States. Understanding the modifiable facility-level factors associated with low transplant rates may inform interventions to improve access to transplantation.

5. Melanson TA, Gander JC, Rossi A, et al. Variation in Waitlisting Rates at the Dialysis Facility Level in the Context of Goals for Improving Kidney Health in the United States. Kidney International Reports 2021;6:1965-1968.

No abstract.

6. Meier-Kriesche, Herwig-Ulf, and Bruce Kaplan. "Waiting time on dialysis as the strongest modifiable risk factor for renal transplant outcomes: A Paired Donor Kidney Analysis." Transplantation 74.10 (2002): 1377-1381.

Abstract: BACKGROUND: Waiting time on dialysis has been shown to be associated with worse outcomes after living and cadaveric transplantation. To validate and quantify end-stage renal disease (ESRD) time as an independent risk factor for kidney transplantation, we compared the outcome of paired donor kidneys, destined to patients who had ESRD more than 2 years compared to patients who had ESRD less than 6 months.

METHODS: We analyzed data available from the U.S. Renal Data System database between 1988 and 1998 by Kaplan-Meier estimates and Cox proportional hazards models to quantify the effect of ESRD time on paired cadaveric kidneys and on all cadaveric kidneys compared to living-donated kidneys.

RESULTS: Five- and 10-year unadjusted graft survival rates were significantly worse in paired kidney recipients who had undergone more than 24 months of dialysis (58% and 29%, respectively) compared to paired kidney recipients who had undergone less than 6 months of dialysis (78% and 63%, respectively; P<0.001 each). Ten-year overall adjusted graft survival for cadaveric transplants was 69% for preemptive transplants versus 39% for transplants after 24 months on dialysis. For living transplants, 10-year overall adjusted graft survival was 75% for preemptive transplants versus 49% for transplants after 24 month on dialysis.

CONCLUSIONS: ESRD time is arguably the strongest independent modifiable risk factor for renal transplant outcomes. Part of the advantage of living-donor versus cadaveric-donor transplantation may be explained by waiting time. This effect is dominant enough that a cadaveric renal transplant recipient with an ESRD time less than 6 months has the equivalent graft survival of living donor transplant recipients who wait on dialysis for more than 2 years.

7. Meier-Kriesche, H. U., Port, F. K., Ojo, A. O., Rudich, S. M., Hanson, J. A., Cibrik, D. M., ... & Kaplan, B. (2000). Effect of waiting time on renal transplant outcome. Kidney international, 58(3), 1311-1317.

Abstract: BACKGROUND: Numerous factors are known to impact on patient survival after renal transplantation. Recent studies have confirmed a survival advantage for renal transplant patients over those waiting on dialysis. We aimed to investigate the hypothesis that longer waiting times are more deleterious than shorter waiting times, that is, to detect a "dose effect" for waiting time.

METHODS: We analyzed 73,103 primary adult renal transplants registered at the United States Renal Data System Registry from 1988 to 1997 for the primary endpoints of death with functioning graft and death-censored graft failure by Cox proportional hazard models. All models were corrected for donor and recipient demographics and other factors known to affect outcome after kidney transplantation.

RESULTS: A longer waiting time on dialysis is a significant risk factor for death-censored graft survival and patient death with functioning graft after renal transplantation (P < 0.001 each). Relative to preemptive transplants, waiting times of 6 to 12 months, 12 to 24 months, 24 to 36, 36 to 48, and over 48 months confer a 21, 28, 41, 53, and 72% increase in mortality risk after transplantation, respectively. Relative to preemptive transplants, waiting times of 0 to 6 months, 6 to 12 months, 12 to 24 months, and over 24 months confer a 17, 37, 55, and 68% increase in risk for death-censored graft loss after transplantation, respectively.

CONCLUSIONS: Longer waiting times on dialysis negatively impact on post-transplant graft and patient survival. These data strongly support the hypothesis that patients who reach end-stage renal disease should receive a renal transplant as early as possible in order to enhance their chances of long-term survival.

8. Schold JD, Huml AM, Poggio ED et al. Patients with High Priority for Kidney Transplant Who Are Not Given Expedited Placement on the Transplant Waiting List Represent Lost Opportunities. J Am Soc Nephrol 2021;32:1733-1746.

Abstract: BACKGROUND: Kidney transplantation is associated with the best outcomes for most patients with ESKD. The national Kidney Allocation System prioritizes patients with Estimated Post-Transplant

Survival (EPTS) scores in the top 20% for expedited access to optimal deceased donor kidneys.

METHODS: We studied adults aged 18 years in the United States Renal Data System with top 20% EPTS scores who had been preemptively waitlisted or initiated dialysis in 2015–2017. We evaluated time to waitlist placement, transplantation, and mortality with unadjusted and multivariable survival models.

RESULTS: Of 42,445 patients with top 20% EPTS scores (mean age, 38.0 years; 57% male; 59% White patients, and 31% Black patients), 7922 were preemptively waitlisted. Among 34,523 patients initiating dialysis, the 3-year cumulative waitlist placement incidence was 37%. Numerous factors independently associated with waitlisting included race, income, and having noncommercial insurance. For example, waitlisting was less likely for Black versus White patients, and for patients in the lowest-income neighborhoods versus those in the highest-income neighborhoods. Among patients initiating dialysis, 61% lost their top 20% EPTS status within 30 months versus 18% of patients who were preemptively listed. The 3-year incidence of deceased and living donor transplantation was 5% and 6%, respectively, for patients who initiated dialysis and 26% and 44%, respectively, for patients who were preemptively listed.

CONCLUSIONS: Many patients with ESKD qualifying with top 20% EPTS status are not placed on the transplant waiting list in a timely manner, with significant variation on the basis of demographic and social factors. Patients who are preemptively listed are more likely to receive benefits of top 20% EPTS status. Efforts to expedite care for qualifying candidates are needed, and automated transplant referral for patients with the best prognoses should be considered.

9. Schold J and Meier-Kreische HU. Which Renal Transplant Candidates Should Accept Marginal Kidneys in Exchange for a Shorter Waiting Time on Dialysis? Clin J Am Soc Nephrol 2006;1:532-538.

Abstract: Renal transplantation has been established as a life-saving procedure for patients with ESRD. Deceased donor kidneys convey variable life expectancies for recipients. However, limited information is available to guide patients and patient advocates concerning the appropriateness to list for expanded criteria donations (ECD). Half-lives for wait-listed transplant candidates were estimated from the time of ESRD onset on the basis of recipient age, primary diagnosis, and organ quality using survival models. In addition, we evaluated the likelihood of candidates' receiving a transplant on the basis of age and other characteristics by duration of waiting time. Older patients (65) had longer life expectancy when they accepted an ECD within 2 yr of ESRD onset (5.6 yr) compared with waiting for a standard kidney (5.3 yr) or a living donation (5.5 yr) after 4 yr of dialysis. Conversely, younger recipients (18 to 39 yr) had longer life expectancy with a living donation (27.6 yr) or standard kidney (26.4 yr) after 4 yr on dialysis compared with an ECD after 2 yr of dialysis (17.6 yr). Increased candidate age was associated with the likelihood of not receiving a transplant during the period on the waiting list as a result of mortality and separately related to morbidity and delisting. Older and frailer transplant candidates benefit from accepting lower quality organs early after ESRD, whereas younger and healthier patients benefit from receiving higher quality organs even with longer dialysis exposure. These findings are important for transplant candidates and advocates decision-making and for potential further implementation in allocation policy.

2.2.2 Performance Scores (NQF Measure Submission Form, Importance to Measure and Report: Gap in Care/Disparities 1b.02)

After applying all exclusion criteria, we evaluated the FYSWR performance scores for all dialysis practitioner group practices that had at least 11 patients and at least 2 expected events in the evaluation period 2016 through 2019. The mean value of FYSWR was 1.01. The interquartile range (Q3-Q1) is 0.77, with the bottom quartile of practitioner group practices having 46% lower, versus the top quartile having 33% higher, waitlisting or living-donor transplant rates among new dialysis patients during their first year of dialysis than the national average. Dates of data: January 1, 2016 – December 31, 2020 (inclusive of data for one year of follow-up beyond last assessment year of 2019).

Number of patients: 281,479

Number of practitioner groups: 2,168

Table 1: *Descriptive statistics of FYSWR overall and by decile, 2016-2019*

	Mean	***Std Dev***	***Minimum***	***Maximum***	***Median***	***Lower Quartile***	***Upper Quartile***
Overall	*1.01*	*0.62*	*0*	*4.85*	*0.92*	*0.56*	*1.33*
*	*	*	*	*	*	*	*
Decile	*	*	*	*	*	*	*
1	*0.13*	*0.12*	*0.00*	*0.31*	*0.14*	*0.00*	*0.25*
2	*0.40*	*0.05*	*0.31*	*0.48*	*0.41*	*0.36*	*0.45*
3	*0.56*	*0.05*	*0.48*	*0.63*	*0.56*	*0.52*	*0.60*
4	*0.71*	*0.04*	*0.64*	*0.78*	*0.72*	*0.67*	*0.75*
5	*0.86*	*0.04*	*0.78*	*0.92*	*0.86*	*0.82*	*0.89*
6	*0.99*	*0.04*	*0.92*	*1.07*	*1.00*	*0.96*	*1.03*
7	*1.15*	*0.05*	*1.07*	*1.24*	*1.14*	*1.10*	*1.19*
8	*1.34*	*0.06*	*1.24*	*1.47*	*1.33*	*1.28*	*1.39*
9	*1.62*	*0.10*	*1.47*	*1.82*	*1.59*	*1.53*	*1.70*
10	*2.31*	*0.45*	*1.82*	*4.85*	*2.16*	*1.98*	*2.53*

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2.2.3 Summary of Data Indicating Opportunity (NQF Measure Submission Form, Importance to Measure and Report: Gap in Care/Disparities 1b.03)

N/A.

2.2.4 Disparities (NQF Submission Form, Importance to Measure and Report: Gap in Care/Disparities 1b.04)

Dates of data: January 1, 2016 – December 31, 2020 (inclusive of data for one year of follow-up beyond last assessment year of 2019).

Number of patients: 281,479

Number of practitioner groups: 2,168

Table 2: *Descriptive statistics of FYSWR, by race, ethnicity and sex, 2016-2019*

Group	***Mean***	***Std Dev***	***Minimum***	***Maximum***	***Median***	***Lower Quartile***	***Upper Quartile***
Race	*	*	*	*	*	*	*
White	*1.13*	*0.94*	*0.00*	*18.21*	*0.99*	*0.55*	*1.52*
Black	*1.05*	*4.97*	*0.00*	*195.92*	*0.58*	*0.00*	*1.13*
Asian Pacific Islander	*2.04*	*9.52*	*0.00*	*286.21*	*0.00*	*0.00*	*1.87*
Native American/ Alaskan Native	*1.89*	*12.32*	*0.00*	*176.88*	*0.00*	*0.00*	*0.00*
Other	*2.88*	*17.33*	*0.00*	*296.55*	*0.00*	*0.00*	*0.00*
*	*	*	*	*	*	*	*
Ethnicity	*	*	*	*	*	*	*
Hispanic	*1.48*	*13.48*	*0.00*	*584.30*	*0.56*	*0.00*	*1.43*
Non-Hispanic	*1.09*	*3.49*	*0.00*	*158.03*	*0.93*	*0.53*	*1.35*
*	*	*	*	*	*	*	*
Sex	*	*	*	*	*	*	*
Female	*0.87*	*0.78*	*0.00*	*5.60*	*0.76*	*0.30*	*1.25*
Male	*1.12*	*0.79*	*0.00*	*5.73*	*1.00*	*0.58*	*1.50*

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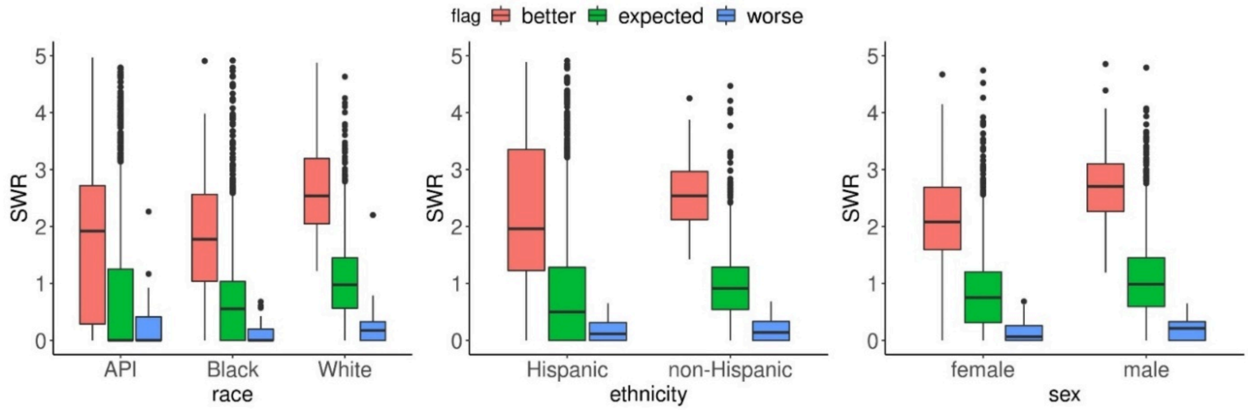
Figure 1*: Performance of FYSWR, by race, ethnicity and sex, 2016-2019*



Note: Race groups Native American/Alaskan Native and Other have only small number of patients and were not included in Figure 1.

The data presented in Table 2 and Figure 1 above demonstrate wide variation and performance gaps within strata of race, ethnicity and sex categories.

2.2.5 Provide summary of data if no or limited data (NQF Submission Form, Importance to Measure and Report: Gap in Care/Disparities 1b.05)

N/A

3. Scientific Acceptability (NQF Scientific Acceptability)

3.1 Data Sample Description (NQF Measure evaluation criterion 2)

3.1.1 What Types of Data Were Used for Testing? (NQF Measure Submission Form, Scientific Acceptability: Reliability - Testing 2a.01)

☐abstracted from paper record
☒administrative claims
☒clinical database/registry
☐abstracted from electronic health record (EHR)
☐electronic clinical quality measure (eCQM) Health Quality Measure Format (HQMF) implemented in EHRs
☐other (specify) Click or tap here to enter text.

Measure tested with data from

☐abstracted from paper record
☒administrative claims
☒clinical database/registry
☐abstracted from EHRs
☐eCQM (HQMF) implemented in EHRs
☐other (specify) Click or tap here to enter text.

3.1.2 Identify the Specific Dataset (NQF Measure Submission Form, Scientific Acceptability: Reliability - Testing 2a.02)

The data are derived from a combination of EQRS (formerly CROWNWeb), CMS Medical Evidence Form (CMS Form 2728), the Nursing Home Minimum Dataset, transplant registries (OPTN, SRTR), and Medicare claims from CMS.

3.1.3 What Are the Dates of the Data Used in Testing? (NQF Measure Submission Form, Scientific Acceptability: Reliability - Testing 2a.03)

01-01-2016 – 12-31-2020 (allowing for one year of follow-up beyond the last year of performance assessment in 2019)

3.1.4 What Levels of Analysis Were Tested? (NQF Measure Submission Form, Scientific Acceptability: Reliability - Testing 2a.04)

Provide testing for all levels specified and intended for measure implementation (e.g., individual clinician, hospital, health plan).

Measure specified to measure performance of (NQF Measure Submission Form, Measure Specifications sp.07)

☐individual clinician
☒group/practice

☐hospital/facility/agency
☐health plan
☐other (specify) Click or tap here to enter text.

Measure tested at level of

☐individual clinician
☒group/practice
☐hospital/facility/agency
☐health plan
☐other (specify) Click or tap here to enter text.

3.1.5 How Many and Which Measured Entities Were Included in the Testing and Analysis? (NQF Measure Submission Form, Scientific Acceptability: Reliability - Testing 2a.05)

Over the reporting period from 2016 through 2019, there were 2,168 practitioner groups included in these analyses, after restricting to practitioner group practices that had at least 11 eligible patients and at least 2 expected events.

3.1.6 How Many and Which Patients Were Included in the Testing and Analysis? (NQF Measure Submission Form, Scientific Acceptability: Reliability - Testing 2a.06)

There were 281,479 patients in total. The average age at their initiation of dialysis was 57.9 years old, 40.9% were female, 63.3% were White, 29.7% were Black, 5.5% were Asian/Pacific Islander, 1.2% were American Indian/Alaskan Native, 0.3% were Other/Multi-racial/Unknown and 17.7% were Hispanic.

3.1.7 Sample Differences, if applicable (NQF Measure Submission Form, Scientific Acceptability: Reliability - Testing 2a.07)

N/A

3.1.8 What Were the Social Risk Factors That Were Available and Analyzed? (NQF Measure Submission Form, Scientific Acceptability: Reliability - Testing 2a.08)

Patient level:

- *Sex (we acknowledge that sex is less recognized as a social risk factor but it is being increasingly considered as such especially given its relationship to gender [see for example, O'Neil et al. Gender/Sex as a social determinant of cardiovascular risk. Circulation 2018;137:854], and have therefore chosen to include an assessment of it in our analysis)*
- *Race*
- *Ethnicity*
- *Medicare-Medicaid dual eligibility*

Data on patient level factors obtained from Medicare claims and administrative data.

Zipcode level – ADI from 2015 Census data.

3.2 Reliability Testing **(for reference only)** (NQF Measure Submission Form, Scientific Acceptability: Reliability – Testing 2a)

3.2.1 Level of Reliability Testing (NQF Measure Submission Form, Scientific Acceptability: Reliability – Testing 2a.09

☐critical data elements used in the measure (e.g., inter-abstractor reliability; data element reliability must address all critical data elements)
☒performance measure score (e.g., signal-to-noise analysis)

3.2.2 Method of Reliability Testing (NQF Measure Submission Form, Scientific Acceptability: Reliability – Testing 2a.10)

We used data from the start of 2016 through the end of 2019 to calculate the First Year Standardized Waitlist Ratio. Our approach for determining measure reliability aligns with one-way analysis of variance (ANOVA), in which the between dialysis practitioner group practice variation (σ_b^2)

and the within- dialysis practitioner group practice variation ($\sigma_{t,w}^2$) *in the measure is determined. The inter-unit reliability (IUR) measures the proportion of the total variation of the measure (i.e.,* $\sigma_b^2 + \sigma_{t,w}^2$) *that is attributed to the between – dialysis practitioner group practice variation, the true signal that reflects the differences across dialysis practitioner group practices. We assessed reliability by calculating inter-unit reliability (IUR) for the annual performance scores. If the measure were an average of the individuals' measurements under the care of one dialysis practitioner group practice, the usual ANOVA approach would be used. The yearly based measure, however, is not a simple average and we instead estimate the IUR using a bootstrap approach, which uses a resampling scheme to estimate the within dialysis practitioner group practice variation that cannot be directly estimated by ANOVA. A small IUR (near 0) reveals that most of the variation of the measures between dialysis practitioner group practices is driven by random noise, indicating the measure would not be a good characterization of the differences among dialysis practitioner group practices. A large IUR (near 1) indicates that most of the variation between dialysis practitioner group practices is due to true differences between dialysis practitioner group practices.*

Below is our approach to calculate IUR.

Let $T_1,\ldots,T_N$ *be the FYSWRs for N practitioner groups. Since the variation in* $T_1,\ldots,T_N$ *is mainly driven by the estimates of dialysis practitioner group practice-specific intercepts* ($\alpha_1,\ldots,\alpha_N$)*, we use their asymptotic distributions to estimate the within-dialysis practitioner group practice variation in FYSWRs. Applying the delta method, we estimate the variance of* T_i *and denote the estimate as* S_i^2*. Calling on formulas from the one-way ANOVA, the within-dialysis practitioner group practice variance in FYSWRs can be estimated by*

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

and the total variation in FYSWRs can be estimated by

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

where n_i *is the number of subjects in the ith practitioner group,* $\overline{T} = \sum n_i T_i \,/\, \sum n_i$, *and*

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

is approximately the average dialysis practitioner group practice size (number of patients per dialysis practitioner group practice). Thus, the $IUR = \sigma_b^2/(\sigma_b^2 + \sigma_{t,w}^2)$ *can be estimated by* $(s_t^2 - s_{t,w}^2)/s_t^2$.

The reliability of FYSWR calculation only included dialysis practitioner group practices with at least 11 patients and at least 2 expected events during the entire year.

3.2.3 Statistical Results from Reliability Testing (NQF Measure Submission Form, Scientific Acceptability: Reliability - Testing 2a.11)

The IUR is 0.64. Dialysis practitioner group practices with < 11 eligible patients and < 2 expected events were excluded from this calculation.

3.2.4 Interpretation (NQF Measure Submission Form, Scientific Acceptability: Reliability – Testing 2a.12)

The value of IUR indicates that about 64% of the variation in the FYSWR measure can be attributed to the between-dialysis practitioner group practice differences (signal) and about 36% of variation to within-dialysis practitioner group practice variation (noise). The value of IUR implies a moderate degree of reliability.

3.3 Validity Testing **(for reference only)** (NQF Measure Submission Form, Scientific Acceptability: Validity - Testing 2b)

3.3.1 Level of Validity Testing (NQF Measure Submission Form, Scientific Acceptability: Validity – Testing 2b.01)

☐critical data elements (Note: Data element validity must address all critical data elements.)
☒performance measure score
☒empirical validity testing
☐systematic assessment of face validity of quality measure score as an indicator of quality or resource use (i.e., is an accurate reflection of performance on quality or resource use and can distinguish good from poor performance)

3.3.2 Method of Validity Testing (NQF Measure Submission Form, Scientific Acceptability: Validity – Testing 2b.02)

Validity of the measure was tested by evaluating the association between the dialysis practitioner group level measure performance, and subsequent mortality and overall transplant rates among all patients attributed to the practitioner groups. We hypothesized that practitioner groups with higher performance on the FYSWR measure would have subsequently higher transplant rates among their patients. This would be expected to follow from activities these practitioner groups conducted to improve the health and therefore suitability of their patients for transplant candidacy. Along similar lines, we hypothesized that practitioner groups with higher performance on the FYSWR measure would demonstrate lower subsequent mortality among their patients. However, we expected this to be a more modest association given the many other factors that can affect mortality within the dialysis population.

To evaluate the associations, we first divided dialysis practitioner groups into 3 tertiles (T1 to T3) based on their performance on the FYSWR (T1 to T3, from highest to lowest waitlisting). Tertiles were chosen in order to evaluate a gradient in effect, but still maintain sufficient numbers within each group for statistical precision. We then computed the corresponding second year mortality rate and transplant rate among patients assigned to each practitioner group. We then applied the Cochran-Armitage trend test to evaluate the relationship between the tertile grouping and these practitioner group-level outcomes. Finally, we examined the Spearman correlations between FYSWR and the second year mortality rate or second year transplant rate.

3.3.3 Statistical Results from Validity Testing (NQF Measure Submission Form, Scientific Acceptability: Validity – Testing 2b.03)

The tertile groups based on the performance scores were defined as:

T_1 *(best performance): 1.17 - 4.85*

T_2*: 0.69 - 1.17*

T_3 *(worst performance): 0 - 0.69*

The dialysis practitioner group average second year mortality is 15.3, 15.7, 15.9 deaths per 100 patient-years for T_1, T_2, T_3 *groups, respectively (trend test p=0.0607). The Spearman correlation coefficient is: -0.02 (p=0.3151).*

The dialysis practitioner group average second year transplant rate is 4.7, 3.2, 1.8 transplants per 100 patient-years for the T_1, T_2, T_3 *groups, respectively (trend test p<.01). The Spearman correlation coefficient is: 0.32 (p<.01).*

3.3.4 Interpretation (NQF Measure Submission Form, Scientific Acceptability: Validity – Testing 2b.04)

As expected, higher FYSWR performance correlated with higher second year transplant rate, with clear separation of transplant rates across practitioner group tertiles of performance. The direction of the relationship with mortality was as expected, with numerically lower mortality with higher performance on the FYSWR measure, though it did not achieve statistical significance.

3.4 Exclusions Analysis **(for reference only)** (NQF Measure Submission Form, Scientific Acceptability: Validity - Other Threats to Validity [Exclusions, Risk Adjustment] 2b)

3.4.1 Method of Testing Exclusions (NQF Measure Submission Form, Scientific Acceptability: Validity - Other Threats to Validity [Exclusions, Risk Adjustment] 2b.16)

In order to evaluate the exclusion criteria, the differences in the number of patients with and without excluding age >= 75, nursing home patients, and hospice patients, were compared. We show the frequency of patients excluded due to each criteria. Additionally, we compared the performance scores before and after exclusions. We do not exclude patients from dialysis practitioner groups with fewer than 11 attributed patients or 2 expected events.

3.4.2 Statistical Results from Testing Exclusions (NQF Measure Submission Form, Scientific Acceptability: Validity - Other Threats to Validity [Exclusions, Risk Adjustment] 2b.17)

Table 5*: Overall number and percentage of patients excluded*

*	***Before age, nursing home, and hospice exclusion***	***After age, nursing home, and hospice exclusion***	***Percentage excluded***
Number of patients	*410,849*	*281,479*	*31.5%*

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Table 6: *Frequency distribution of patient-months excluded based on each exclusion criteria*

Variable excluded	***Frequency (%)***
Age >=75	*101,658 (24.7)*
Nursing Home from CMS-2728	*18,178 (4.4)*
Nursing home from Nursing home history file	*9,390 (2.3)*
Hospice	*144 (0.04)*

Table 7: *Distribution of performance scores before and after exclusion*

FYSWR	***Mean***	***Standard Deviation***	***Minimum***	***Q1***	***Median***	***Q3***	***Maximum***
Before exclusion	*1.006*	*0.622*	*0*	*0.563*	*0.924*	*1.330*	*5.238*
After exclusion	*1.007*	*0.623*	*0*	*0.560*	*0.922*	*1.331*	*4.846*

Figure 2: *Distribution of FYSWR before exclusions*

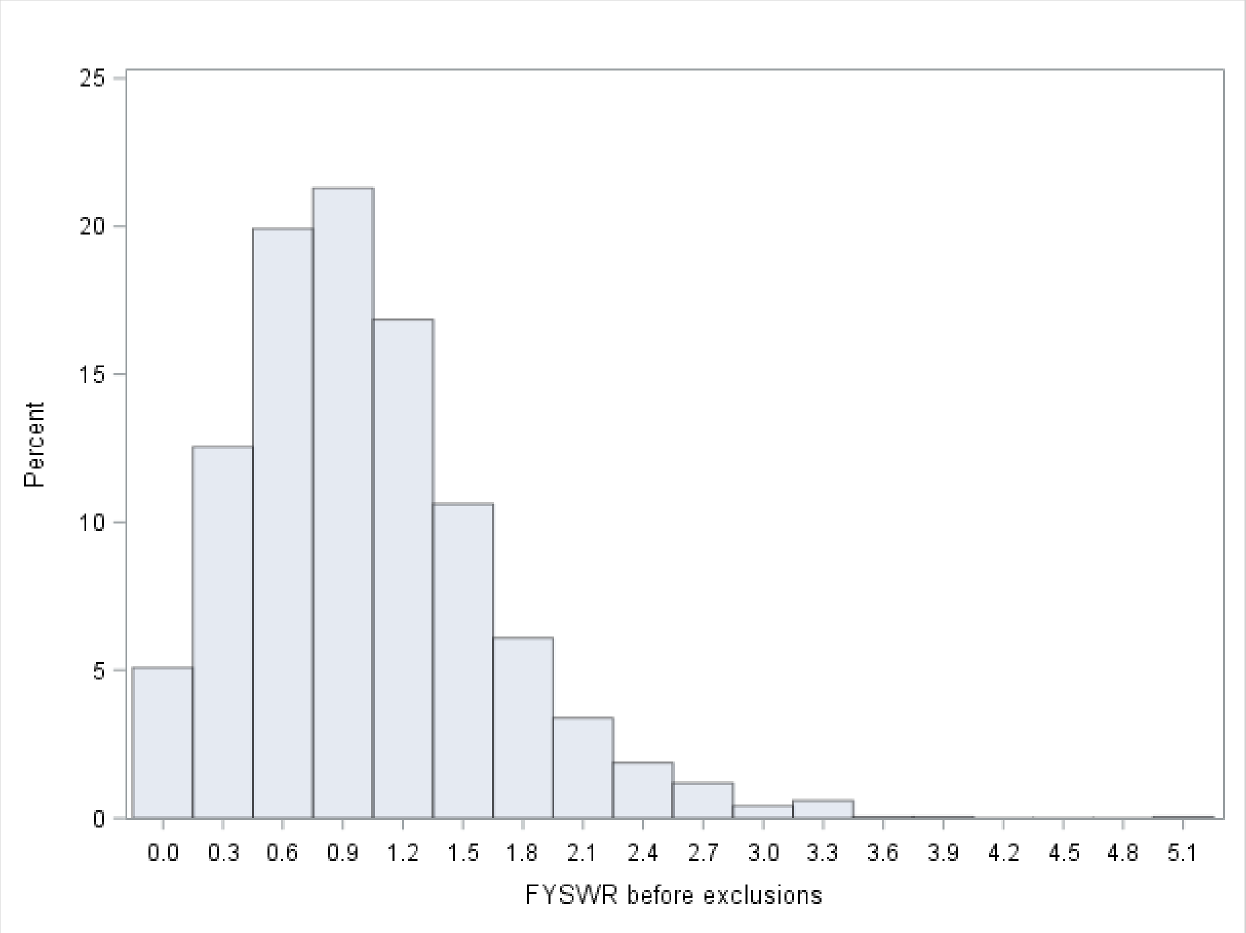


Figure 3: *Distribution of FYSWR after exclusions*

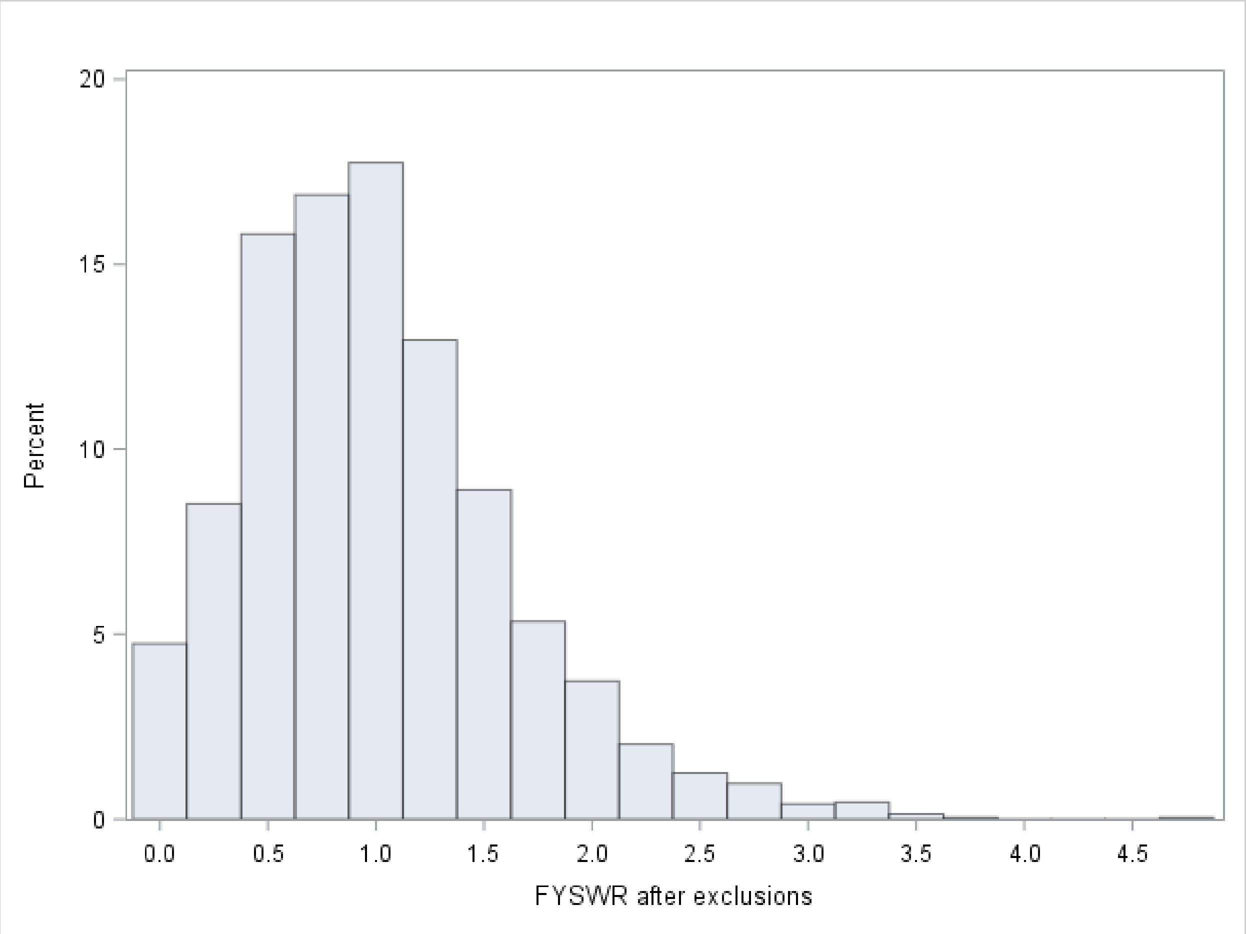
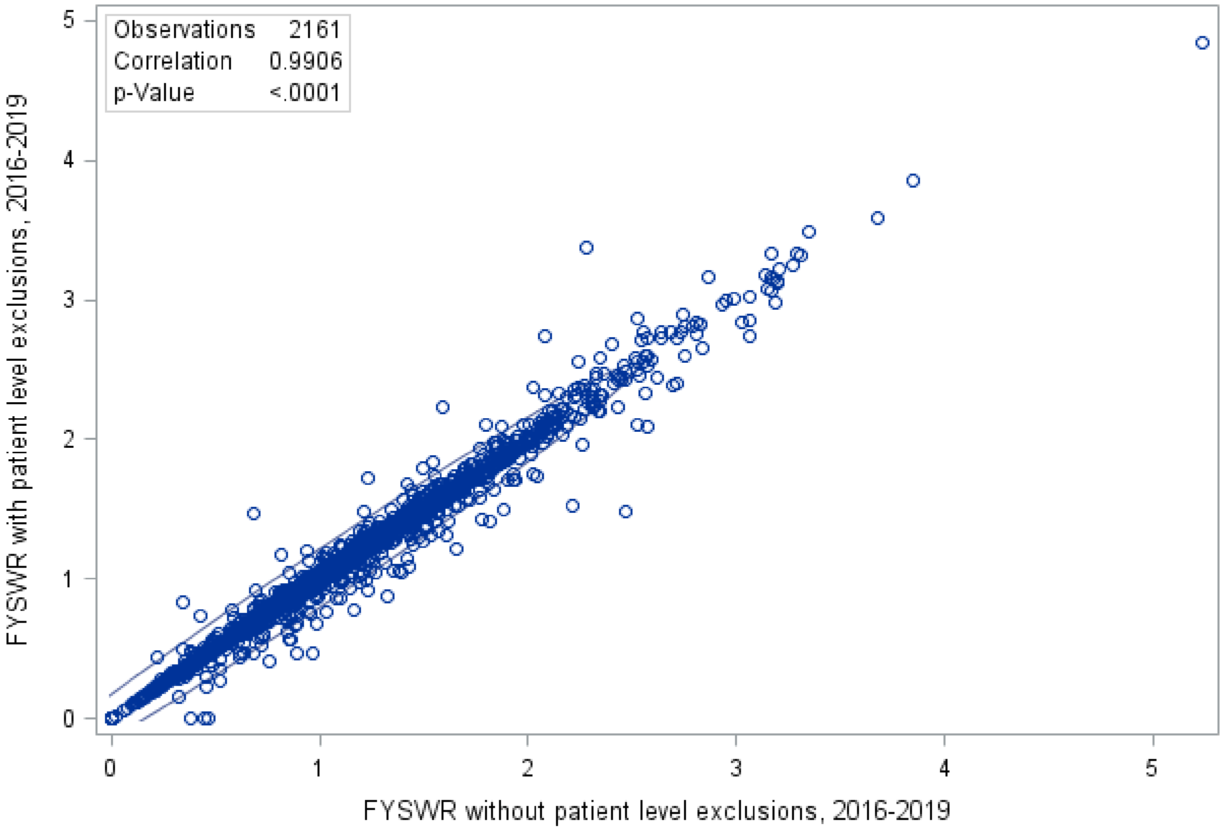


Figure 4: *Scatterplot of FYSWR with and without exclusions*



The correlation coefficient is 0.9906 (p<.0001).

Table 8: *Comparison of performance scores with and without excluded patients*

*	*	***FYSWR without patient-level exclusion***	***FYSWR without patient-level exclusion***	***FYSWR without patient-level exclusion***	***FYSWR without patient-level exclusion***
*	*	***Better than Expected***	***As Expected***	***Worse than Expected***	***Total***
FYSWR with patient-level exclusion	***Better than Expected***	*66*	*15*	*0*	*81*
FYSWR with patient-level exclusion	***As Expected***	*7*	*2,005*	*14*	*2,026*
FYSWR with patient-level exclusion	***Worse than Expected***	*0*	*4*	*50*	*54*
FYSWR with patient-level exclusion	***Total***	*73*	*2,024*	*64*	*2,161*

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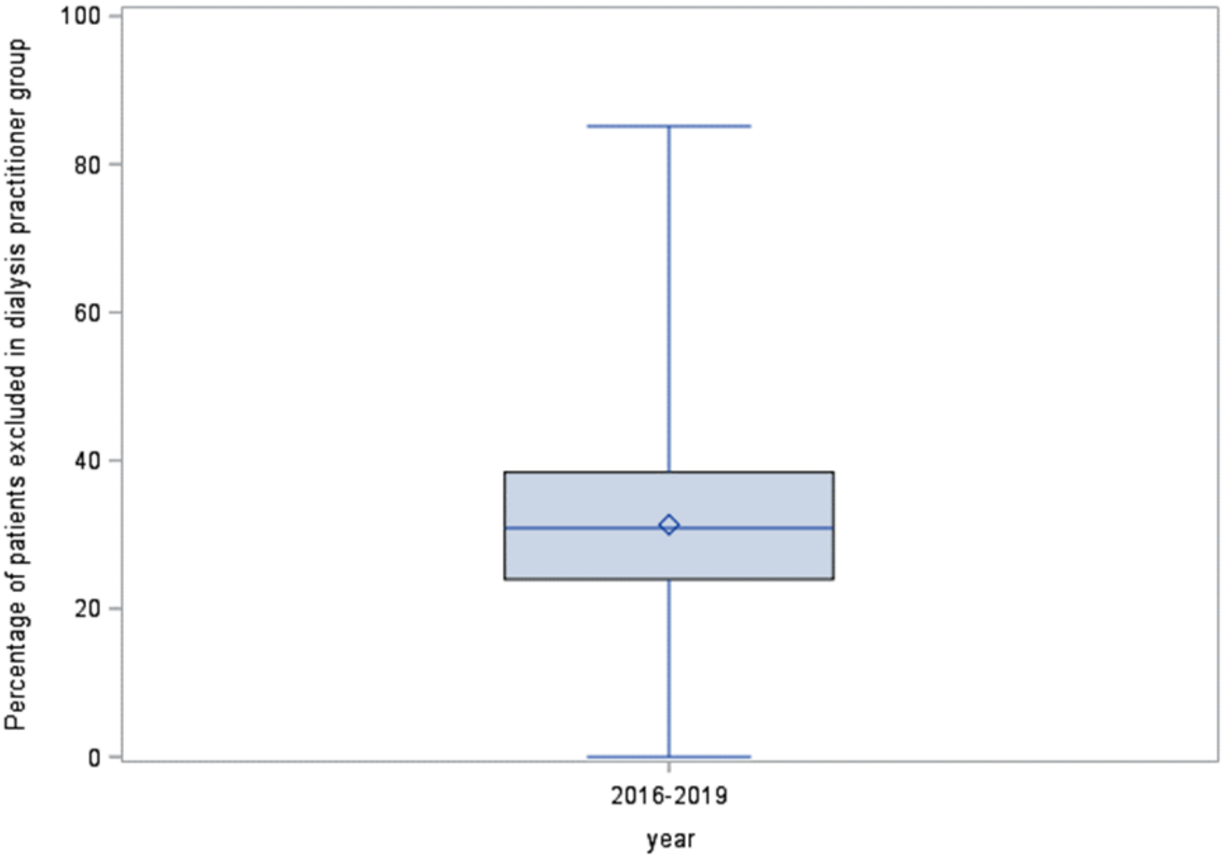
Figure 5: *Distribution of excluded patients (%) across dialysis practitioner group practices*



3.4.3 Interpretation (NQF Measure Submission Form, Scientific Acceptability: Validity - Other Threats to Validity [Exclusions, Risk Adjustment] 2b.18)

Although performance scores are modestly affected by the exclusions (table 7-8, and figures 2-4), the exclusions are deemed important on clinical grounds as they represent a group of patients highly unlikely to be suitable for transplant waitlisting. Furthermore, there is a fair degree of variation in the percentage of patients excluded across practitioner groups, as shown in Figure 5. Finally, as the data to determine the exclusions is readily available, there is minimal additional burden for analysis anticipated by using these exclusion criteria.

3.5 Risk Adjustment or Stratification for Outcome or Resource Use Measures **(for reference only)** (NQF Measure Submission Form, Scientific Acceptability: Validity - Other Threats to Validity [Exclusions, Risk Adjustment] 2b)

3.5.1 Method of Controlling for Differences (NQF Measure Submission Form, Scientific Acceptability: Validity - Other Threats to Validity [Exclusions, Risk Adjustment] 2b.19)

The method of controlling for differences in case mix is

☐no risk adjustment or stratification
☒statistical risk model with (specify number) risk factors

☐stratification by (specify number) risk categories
☐other (specify) Click or tap here to enter text.

3.5.2 Rationale for Why There Is No Need for Risk Adjustment (NQF Measure Submission Form, Scientific Acceptability: Validity - Other Threats to Validity [Exclusions, Risk Adjustment] 2b.21)

N/A

3.5.3 Conceptual, Clinical, and Statistical Methods (NQF Measure Submission Form, Scientific Acceptability: Validity - Other Threats to Validity [Exclusions, Risk Adjustment] 2b.20)

Table 9. *Patient characteristics included in the model as covariate variables and the data source.*

Variable	***Data Source***	***Notes***
Age	*EQRS (formerly CROWNWeb)/SAF*	*Age of Patient*
Age Spline 12	*EQRS (formerly CROWNWeb)/SAF*	*Changes Slope of Age Coefficient at 12*
Age Spline 18	*EQRS (formerly CROWNWeb)/SAF*	*Changes Slope of Age Coefficient at 18*
Age Spline 64	*EQRS (formerly CROWNWeb)/SAF*	*Changes Slope of Age Coefficient at 64*
Heart Disease	*CMS Form 2728 Box 16*	*Binary Variable for Atherosclerotic Heart Disease, Other Cardiac Disease, Cardiac Failure*
Do not Ambulate	*CMS Form 2728 Box 16*	*Binary Variable '1' has disease, '0' does not*
COPD	*CMS Form 2728 Box 16*	*Binary Variable '1' has disease, '0' does not*
Do not Transfer	*CMS Form 2728 Box 16*	*Binary Variable '1' has disease, '0' does not*
Cancer	*CMS Form 2728 Box 16*	*Binary Variable '1' has disease, '0' does not*
Peripheral Vascular Disease	*CMS Form 2728 Box 16*	*Binary Variable '1' has disease, '0' does not*
Cerebral Vascular Accident	*CMS Form 2728 Box 16*	*Binary Variable '1' has disease, '0' does not*
Drug Use	*CMS Form 2728 Box 16*	*Binary Variable '1' has disease, '0' does not*
Amputation	*CMS Form 2728 Box 16*	*Binary Variable '1' has disease, '0' does not*
Assistance with Daily Activities	*CMS Form 2728 Box 16*	*Binary Variable '1' has disease, '0' does not*
Area Deprivation Index (ADI)	*U.S. Census Data*	*Continuous 0 to 1 Index; Higher Values Indicate Higher Neighborhood Disadvantage*
Medicare Dual Eligible	*CMS Form 2728 Box 11/ EQRS (formerly CROWNWeb) Enrollment Database*	*Binary Variable '1' is Medicare and Medicaid at Incidence, '0' is not*

Variable	***Data Source***	***Notes***
Weighted SRTR mortality ratio	*SRTR Program-Specific Reports*	*Ratio is weighted by the percentage of dead patients in each transplant center in the same patient residential area*
Weighted SRTR transplant ratio	*SRTR Program-Specific Reports*	*Ratio is weighted by the percentage of waitlisted patients placed on each transplant center in the same patient residential area*

For the measure outcome, the event was defined as waitlisting or living-donor transplantation. Time zero was defined as the first initiation of dialysis. Patients were followed until waitlisting, living donor transplantation, death, or one-year anniversary since first dialysis (i.e., the earliest thereof). A two-stage Cox model was fitted to calculate the expected number of events. At the first stage, a Cox model stratified on dialysis practitioner group practices was fitted in order to obtain an estimate of the age, comorbidities, and transplant center effects (unconfounded by dialysis practitioner group practices) to be used as an offset. At the second stage, a national average baseline hazard was estimated. The national average baseline (from the second stage), age, comorbidities, and transplant center adjustments (from the first stage) were then used to compute the probability of an event for each patient, followed by the total expected number of events at each dialysis practitioner group practice.

Let p denote the number of patient characteristics in the model and X_{ij} *be the specific value of the* j^{th} *characteristic for the* i^{th} *patient-record. At the first stage, for patient-record i, we denote the measured characteristics or covariates as* $X_i = (\chi_{i1}, \chi_{i2}, \ldots, \chi_{ip},)$ *and use this to define the regression portion of a Cox model in which dialysis practitioner group practices define the strata. Note that for a categorical characteristic, the* X_{ij} *value is 1 if the patient falls into the category and 0 otherwise. The output of the first stage is a set of regression coefficients,* $\beta_1, \beta_2, \ldots, \beta_p$ *and the corresponding predicted value for the* i^{th} *patient-record is given by*

$$\chi_i\beta = (\beta_{1\chi_{i1}} + \beta_{2\chi_{i2}} + \ldots + \beta_{p\chi_{ip}}) \quad (1)$$

At the second stage, the relative risk estimates from the first stage were used as an offset, without stratification. After the second stage, the linear prediction is

$$A_i = \beta_{0\chi_{i0}} + X_i\beta = \beta_{0\chi_{i0}} + \beta_{1\chi_{i1}} + \beta_{2\chi_{i2}} + \ldots + \beta_{p\chi_{ip}} \quad (2)$$

Suppose that t_i *is the end of follow-up time for patient-record i, so that* $S_0(t_i)$ *is the baseline survival probability at time* t_i*. The survival probability for this patient-record i at time* t_i *is:*

$$S_i(t_i) = [\mathrm{S}_0(t_i)]^{exp(A_i)}. \quad (3)$$

The expected number of waitlistings for this patient-record during follow-up time t_i *arises from considerations in the Cox model and can be written as*

$$-ln(S_i(t_i)) = -e^{A_i} ln(S_0(t_i)). \quad (4)$$

The expected number of waitlistings at a given dialysis practitioner group practice can now be computed simply by summing these expected values over the totality of patient-records at that dialysis practitioner group practices. Specifically, the expected value is the sum over the N patient-records at the dialysis practitioner group practices giving

$$E = \sum_{i=1}^{N} - ln(S_i(t_i)) = -\sum_{i=1}^{N} e^{A_i} ln(S_0(t_i)). \quad (5)$$

Let O be the total number of waitlisting observed at the dialysis practitioner group practice during the total four years follow-up period. As stated above, the FYSWR is the ratio of the total number of observed waitlisting to the expected number

FYSWR= O/E. *(6)*

3.5.4 Conceptual Model of Impact of Social Risks (NQF Measure Submission Form, Scientific Acceptability: Validity - Other Threats to Validity [Exclusions, Risk Adjustment] 2b.22)

☒published literature
☒internal data analysis
☐other (specify) Click or tap here to enter text.

3.5.5 Statistical Results (NQF Measure Submission Form, Scientific Acceptability: Validity - Other Threats to Validity [Exclusions, Risk Adjustment] 2b.24)

Table 10. *Model statistics for risk factors in FYSWR model*

Variable	***Hazard Ratio***	***95% Confidence Interval***
Age (continuous)	*1.10*	*(1.08, 1.12)*
Age Spline 12	*0.82*	*(0.79, 0.85)*
Age Spline 18	*1.07*	*(1.05, 1.10)*
Age Spline 64	*0.92*	*(0.91, 0.93)*
Heart Disease	*0.55*	*(0.53, 0.57)*
Do not Ambulate	*0.41*	*(0.34, 0.48)*
COPD	*0.42*	*(0.38, 0.46)*
Do not Transfer	*0.67*	*(0.49, 0.90)*
Cancer	*0.58*	*(0.54, 0.63)*
Peripheral Vascular Disease	*0.67*	*(0.63, 0.72)*
Cerebral Vascular Accident	*0.58*	*(0.54, 0.62)*
Drug Use	*0.18*	*(0.15, 0.21)*
Amputation	*0.50*	*(0.45, 0.55)*
Assistance with Daily Activities	*0.57*	*(0.54, 0.62)*
Area Deprivation Index (ADI), per 10% increase on the percentile scale	*0.87*	*(0.86, 0.88)*
Medicare-Medicaid Dual Eligible	*0.57*	*(0.54, 0.60)*
Transplant center weighted SRTR mortality ratio	*1.39*	*(1.18, 1.64)*
Transplant center weighted SRTR transplant ratio	*1.04*	*(0.97, 1.11)*

3.5.6 Analyses and Interpretation in Selection of Social Risk Factors (NQF Measure Submission Form, Scientific Acceptability: Validity - Other Threats to Validity [Exclusions, Risk Adjustment] 2b.25)

As noted in section 2b.23, we included Medicare-Medicaid dual eligibility and ADI as social risk factors in the model on a clinical and conceptual basis, and as supported by an expert panel. Both factors were significantly associated with the outcome of waitlisting (see Table 10 in 2b.24).

We additionally examined selected variables, including sex, race and ethnicity, fitting models including covariates from the original model and adding each selected variable one at a time.

Table 11. *Hazard Ratio and 95% Confidence Interval of model including sex*

Sex	***Hazard Ratio***	***95% Confidence Interval***
Female	*0.82*	*(0.80,0.84)*
Male	*Reference*	*Reference*

Table 12. *Hazard Ratio and 95% Confidence Interval of model including race*

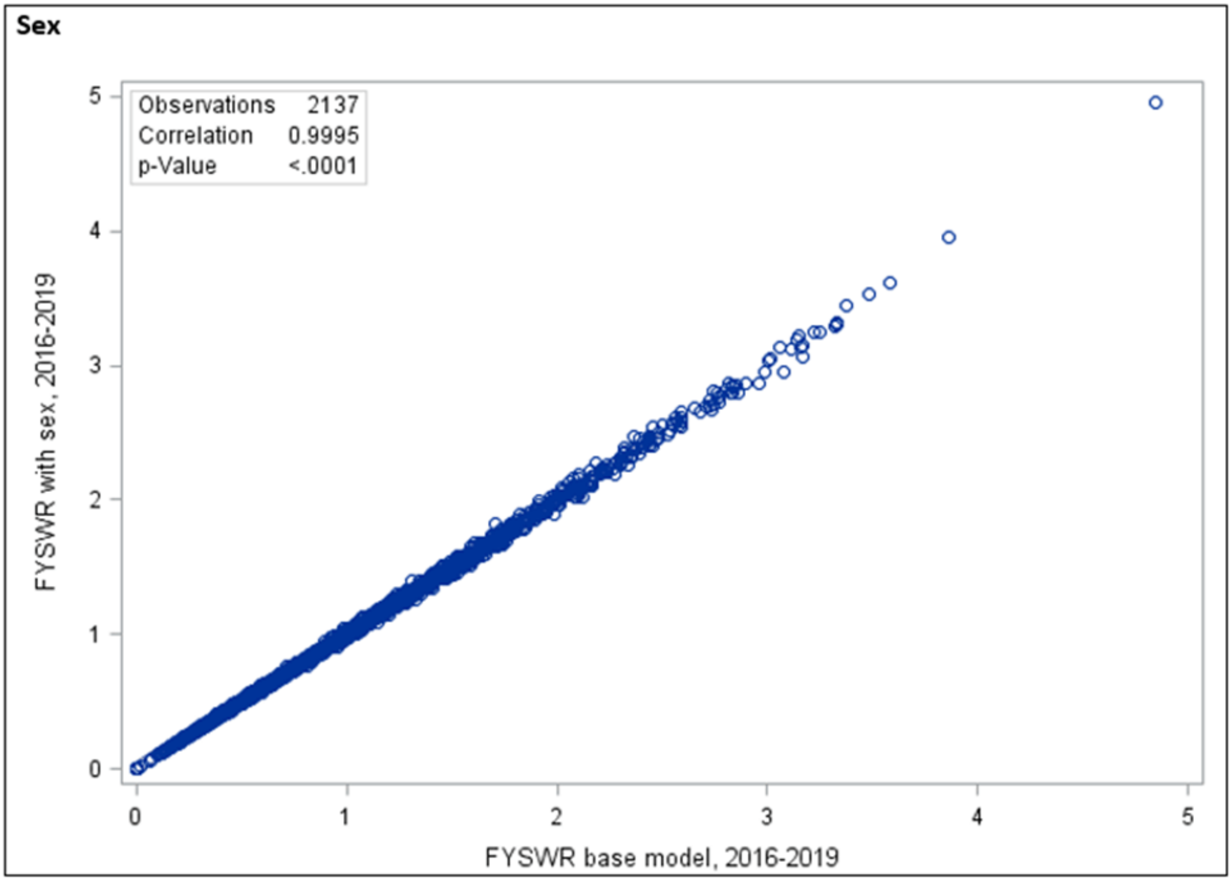
Race	***Hazard Ratio***	***95% Confidence Interval***
Native American	*0.56*	*(0.49,0.65)*
Asian Pacific Islander	*1.11*	*(1.06,1.17)*
Black	*0.72*	*(0.70,0.75)*
Other	*0.89*	*(0.73,1.07)*
White	*Reference*	*Reference*

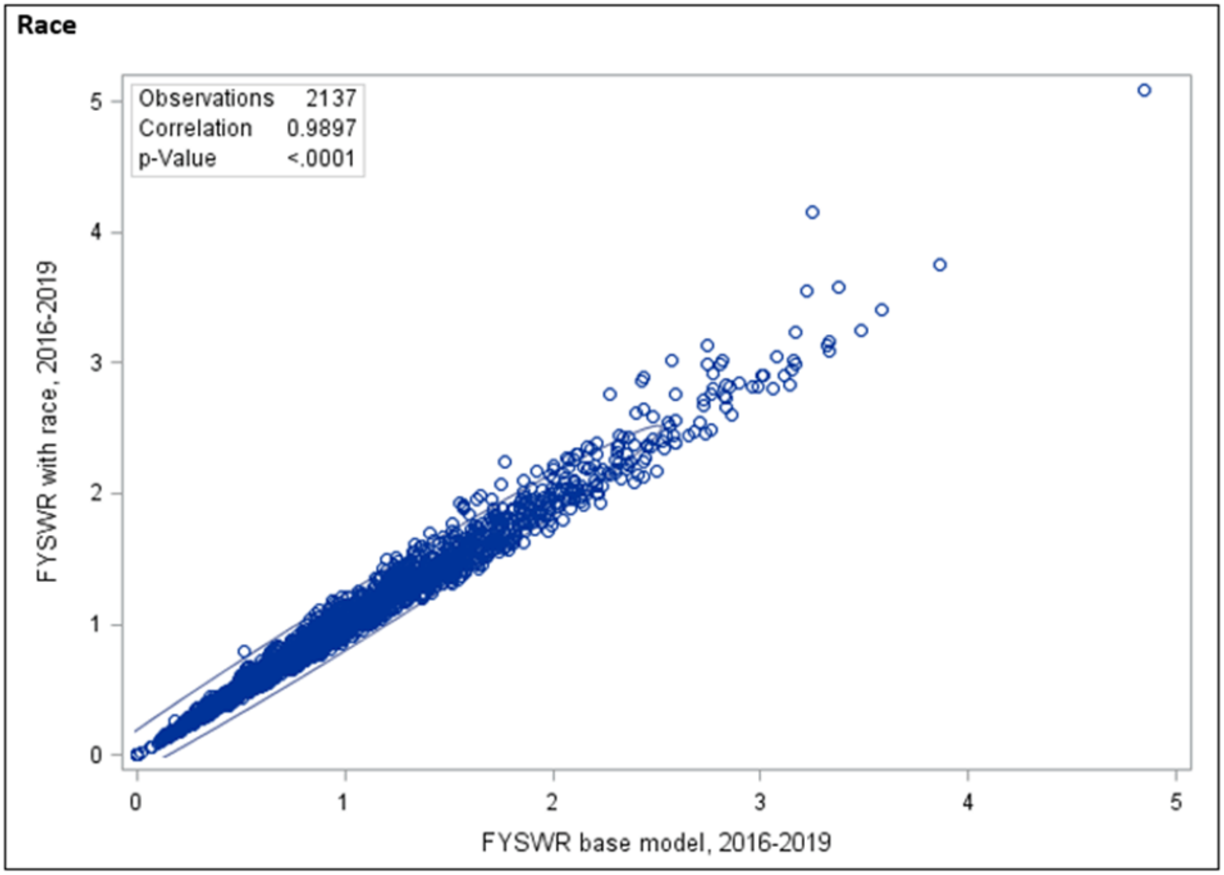
Table 13. *Hazard Ratio and 95% Confidence Interval of model including ethnicity*

Ethnicity	***Hazard Ratio***	***95% Confidence Interval***
Hispanic	*1.00*	*(0.97,1.04)*
Non-Hispanic	*Reference*	*Reference*

Compared to men, female patients were less likely to be waitlisted (Hazard ratio = 0.82). Compared to White patients, Asian & Pacific Islanders were more likely to be waitlisted (Hazard ratio = 1.11). Black and Native American patients were less likely to get waitlisted compared with White patients (Hazard ratio = 0.72 and 0.56, respectively). The waitlisting rate for Hispanic patients was not significantly different from Non-Hispanic patients.

Figure 6: *Correlation between FYSWR with and without each risk factor*





Race

Observations 2137
Correlation 0.9897
p-Value <.0001
FYSWR with race, 2016-2019
FYSWR base model, 2016-2019
0
1
2
3
4
5

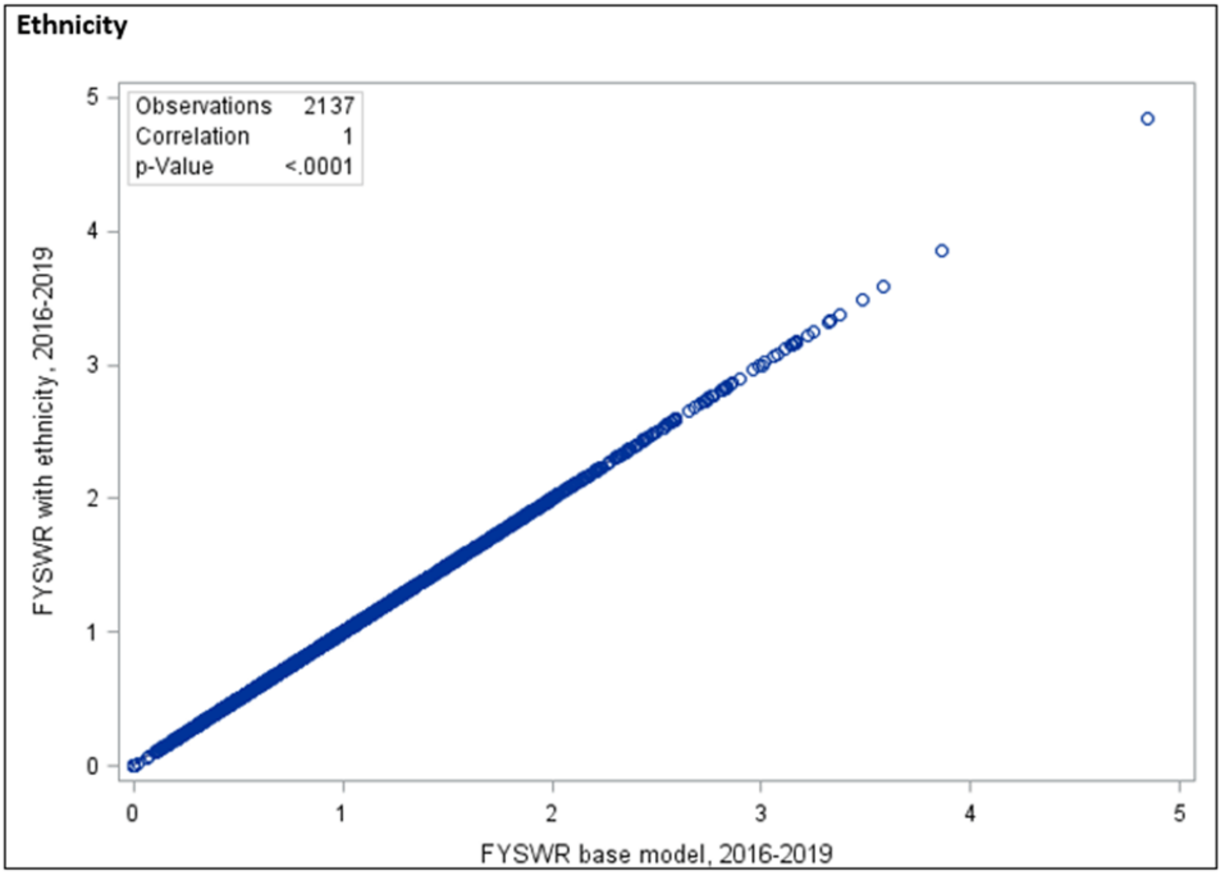


Table 14: *Comparison of performances with and without adjusting for risk factors*

*	*	***FYSWR without sex***	***FYSWR without sex***	***FYSWR without sex***	***FYSWR without sex***
*	*	***As Expected***	***Better than Expected***	***Worse than Expected***	***Total***
FYSWR with sex	***As Expected***	*1,992*	*2*	*0*	*1,994*
FYSWR with sex	***Better than Expected***	*2*	*79*	*0*	*81*
FYSWR with sex	***Worse than Expected***	*8*	*0*	*54*	*62*
FYSWR with sex	***Total***	*2,002*	*81*	*62*	*2,137*

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*	*	FYSWR without race	FYSWR without race	FYSWR without race	FYSWR without race
*	*	As Expected	Better than Expected	Worse than Expected	Total
FYSWR with race	As Expected	1,985	10	6	2,001
FYSWR with race	Better than Expected	5	71	0	76
FYSWR with race	Worse than Expected	12	0	48	60
FYSWR with race	Total	2,002	81	54	2,137

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*	*	***FYSWR without ethnicity***	***FYSWR without ethnicity***	***FYSWR without ethnicity***	***FYSWR without ethnicity***
*	*	***As Expected***	***Better than Expected***	***Worse than Expected***	***Total***
FYSWR with ethnicity	***As Expected***	*1,995*	*1*	*0*	*1,996*
FYSWR with ethnicity	***Better than Expected***	*2*	*80*	*0*	*82*
FYSWR with ethnicity	***Worse than Expected***	*5*	*0*	*54*	*59*
FYSWR with ethnicity	***Total***	*2,002*	*81*	*54*	*2,137*

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Although there are differences in waitlisting by sex and race, it is unclear whether these associations are due to underlying biological or other patient factors, or represent disparities in care. Adjusting for these factors could have the unintended consequence of creating or reinforcing disparities. Furthermore, Tables 11-14 and Figure 6 show that adjustment for these factors had minimal impact on dialysis practitioner group performance. Therefore, these risk factors were not included in the final risk adjusted model.

3.5.7 Method Used to Develop the Statistical Model or Stratification Approach (NQF Measure Submission Form, Scientific Acceptability: Validity - Other Threats to Validity [Exclusions, Risk Adjustment] 2b.26)

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

3.5.8 Statistical Risk Model Discrimination Statistics (e.g., c-statistic, R^2) (NQF Measure Submission Form, Scientific Acceptability: Validity - Other Threats to Validity [Exclusions, Risk Adjustment] 2b.27)

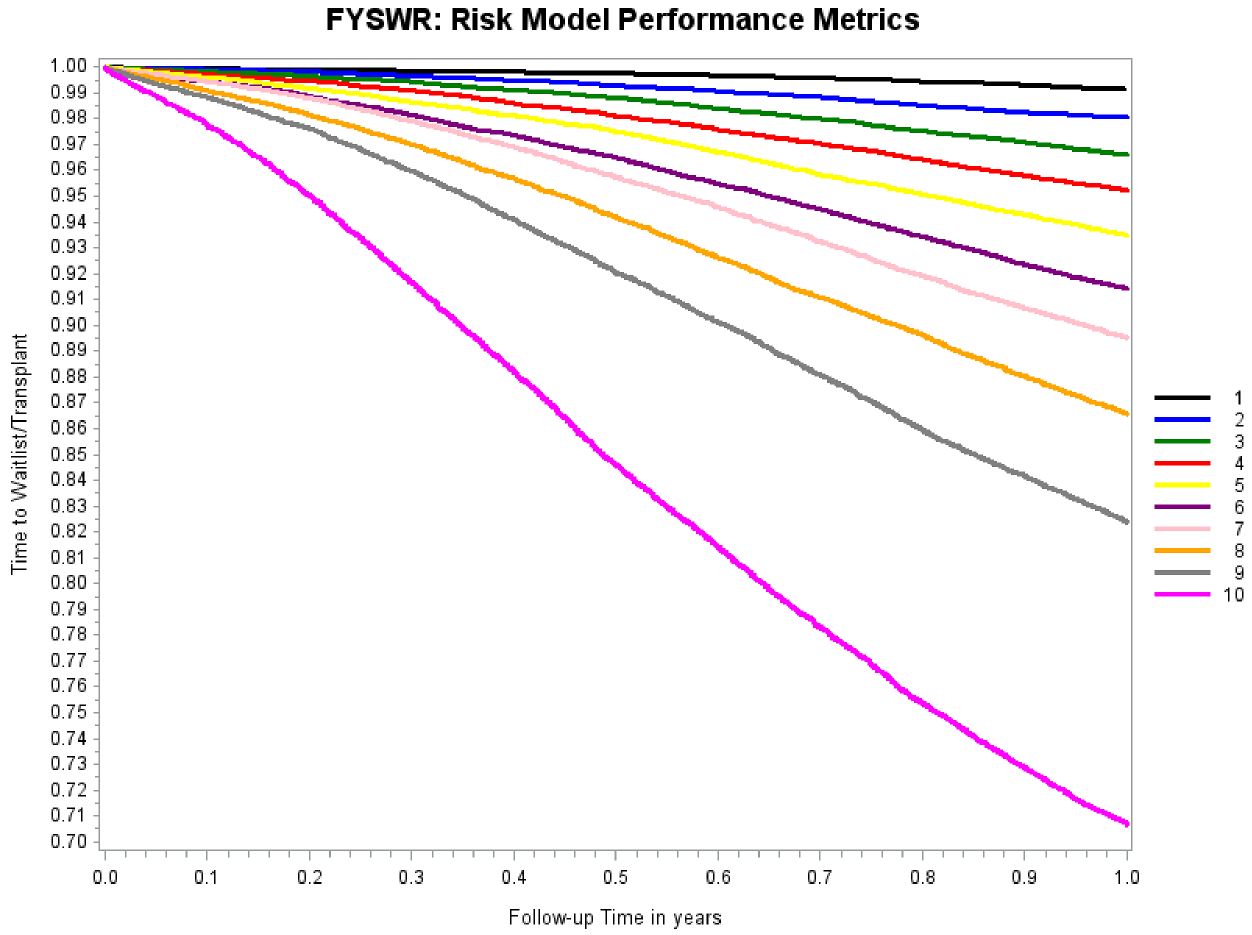
The C-statistic (also known as the Index of Concordance) was 0.75, meaning that the model correctly ordered 75% of the pairs of patient-months that were discordant with respect to the response variate.

3.5.9 Statistical Risk Model Calibration Statistics (e.g., Hosmer-Lemeshow statistic) (NQF Measure Submission Form, Scientific Acceptability: Validity - Other Threats to Validity [Exclusions, Risk Adjustment] 2b.28)

N/A

3.5.10 Statistical Risk Model Calibration—Risk decile plots or calibration curves (NQF Measure Submission Form: Other Threats to Validity [Exclusions, Risk Adjustment] 2b.29)

Figure 7: *Decile plot for FYSWR*



3.5.11 Results of Risk Stratification Analysis (NQF Measure Submission Form, Scientific Acceptability: Validity - Other Threats to Validity (Exclusions, Risk Adjustment) 2b.30)

N/A

3.5.12 Interpretation (NQF Measure Submission Form, Scientific Acceptability: Validity - Other Threats to Validity [Exclusions, Risk Adjustment] 2b.31)

Figure 7 shows that the risk factors in the model are discriminating well between patients. There is good separation among all 10 groups and the ordering is as predicted by the model. Patients of higher model deciles are much more likely to waitlist or transplant than lower model deciles showing effectiveness of the model to discriminate likelihood of waitlisting.

3.5.13 Optional Additional Testing for Risk Adjustment (NQF Measure Submission Form, Scientific Acceptability: Validity - Other Threats to Validity [Exclusions, Risk Adjustment] 2b.32)

N/A

3.6 Identification of Meaningful Differences in Performance **(for reference only)** (NQF Measure Submission Form: Scientific Acceptability: Validity - Threats to Validity [Statistically Significant Differences, Multiple Data Sources, Missing Data] 2b)

3.6.1 Method (NQF Measure Submission Form: Scientific Acceptability: Validity - Threats to Validity [Statistically Significant Differences, Multiple Data Sources, Missing Data] 2b.05)

Dialysis practitioner groups were classified as 'As Expected,' 'Better than Expected', or 'Worse than Expected' based on whether observed and expected values are statistically different at the 5% level. Average values of FYSWR between these groups are listed to determine if there are practically meaningful differences in performance scores. Specifically, the p-value is computed using a Poisson approximation under which the distribution of the observed number, O, in the dialysis practitioner group is Poisson with a mean value equal to the expected number, E, computed from the Cox model. Accordingly, if the observed number, O, is greater than E, then the mid p-value = $Pr(X>=O)+ Pr(X>O)$ where X has a Poisson distribution with mean E. Similarly, if $O<E$, the mid p-value = $Pr(X <=O)+ Pr(X<O)$ where X has a Poisson distribution with mean E. To address the problem of simultaneously monitoring a large number of dialysis practitioner groups and to take account of the intrinsic unexplained variation among practitioner groups, we used the approach described in Kalbfleisch and Wolfe (see full citation below). Specifically, to implement this method, the p-value for each dialysis practitioner group is converted to a Z-score, stratified into four groups based on patient-years within each practitioner group. Within each group, using robust estimates of location and scale based on the normal curve fitted to the center of the z-scores, we derive the mean and variance of a normal empirical null distribution. This empirical null distribution is then used to calculate the p-value for each dialysis practitioner. Finally, dialysis practitioner group practices are flagged if they have outcomes that are extreme when compared to the variation in the national waitlist rate. This method aims to separate underlying intrinsic variation in dialysis practitioner group outcomes from variation that might be attributed to poor (or excellent) care.

Reference:
Kalbfleisch, J. and Wolfe, R. (2013). On monitoring outcomes of medical providers. Statistics in Biosciences, 5(2):286–302.

3.6.2 Statistical Results (NQF Measure Submission Form: Scientific Acceptability: Validity - Threats to Validity [Statistically Significant Differences, Multiple Data Sources, Missing Data] 2b.06)

Table 3: *Count (%) of dialysis practitioner group practices and median FYSWR, stratified by classification category.*

Classification Category	***Count***	***Percent***	***Median FYSWR***
Better Than Expected	*81*	*4%*	*2.59*
As Expected	*2,033*	*94%*	*0.97*
Worse Than Expected	*54*	*2%*	*0.19*
Total	*2,168*	*100%*	*0.92*

3.6.3 Interpretation (NQF Measure Submission Form: Scientific Acceptability: Validity - Threats to Validity [Statistically Significant Differences, Multiple Data Sources, Missing Data] 2b.07)

Four percent of dialysis practitioner group practices were classified as better than expected and 2% as worse than expected. Better than expected physician group on average have observed waitlist/living donor transplant rates more than double that of expected waitlist/transplant rates while worse than expected dialysis practitioner group practices had observed rates less than 1/5 what was expected. These differences are therefore both practically meaningful and statistically significant.

3.7 Comparability of Multiple Data Sources/Methods **(for reference only)** (NQF Measure Submission Form: Scientific Acceptability: Validity - Threats to Validity [Statistically Significant Differences, Multiple Data Sources, Missing Data] 2b)

3.7.1 Method (NQF Measure Submission Form: Scientific Acceptability: Validity - Threats to Validity [Statistically Significant Differences, Multiple Data Sources, Missing Data] 2b.12)

N/A

3.7.2 Statistical Results (NQF Measure Submission Form: Scientific Acceptability: Validity - Threats to Validity [Statistically Significant Differences, Multiple Data Sources, Missing Data] 2b.13)

N/A

3.7.3 Interpretation (NQF Measure Submission Form: Scientific Acceptability: Validity - Threats to Validity [Statistically Significant Differences, Multiple Data Sources, Missing Data] 2b.14)

N/A

3.8 Missing Data Analysis and Minimizing Bias **(for reference only)** (NQF Measure Submission Form: Scientific Acceptability: Validity - Threats to Validity [Statistically Significant Differences, Multiple Data Sources, Missing Data])

3.8.1 Method (NQF Measure Submission Form: Scientific Acceptability: Validity - Threats to Validity [Statistically Significant Differences, Multiple Data Sources, Missing Data] 2b.08)

Many data elements can be obtained from multiple sources and missing data occurs rarely for variables included in this measure. One element with missingness is with respect to assignment of dialysis practitioner groups, which occurs for one of following two reasons: 1) some patients could not be assigned to a dialysis practitioner group due to missing National Provider Identifier (NPI)/Unique

Physician Identifier Number (UPIN) information on the CMS-2728 form, or 2) because the NPI/UPIN could not be matched with the most current and active practitioner group from the IDR provider table.

3.8.2 Missing Data Analysis (NQF Measure Submission Form: Scientific Acceptability: Validity - Threats to Validity [Statistically Significant Differences, Multiple Data Sources, Missing Data] 2b.09)

Table 4: *Distribution of missing data among 281,479 patients in the performance assessment period 2016-2019*

*	*Count*	*Percent*
Patients with no practitioner NPI on 2728, or without a match to the most current and active practitioner group from the IDR provider table	*17,654*	*6.2*

**This cell is intentionally left blank.*

3.8.3 Interpretation (NQF Measure Submission Form: Scientific Acceptability: Validity - Threats to Validity [Statistically Significant Differences, Multiple Data Sources, Missing Data] 2b.10)

Only 6.2% of patients are missing a dialysis practitioner group. Patients with missing dialysis practitioner assignment were aggregated into their own group and also included in the statistical model used to obtain the performance scores. The FYSWR was 1.05 for patients in the missing dialysis practitioner group, which was not statistically significant from the average score, suggesting that these missing patients have similar waitlisting experience to the average.

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

4. Feasibility (NQF Feasibility Criterion 3)

4.1 Data Elements Generated as Byproduct of Care Processes (NQF Measure Submission Form, Feasibility 3.01)

Data used in the measure are (check all that apply)

- ☒generated or collected by and used by healthcare personnel during provision of care (e.g., blood pressure, laboratory value, diagnosis, depression score)
- ☒coded by someone other than the person obtaining original information (e.g., Diagnosis-Related Group [DRG], International Classification of Diseases, 10th Revision, Clinical Modification/Procedure Coding System [ICD-10-CM/PCS] codes on claims)

☐abstracted from a record by someone other than the person obtaining original information (e.g., chart abstraction for quality measure or registry)
☐other (specify) Click or tap here to enter text.

4.2 Electronic Sources

4.2.1 Data Elements Electronic Availability (NQF Measure Submission Form, Feasibility 3.02.)

To what extent are the data elements needed for the measure available electronically (i.e., needed elements to compute quality measure scores are in defined, computer-readable fields)?

☐All data elements are in defined fields in EHRs.
☐All data elements are in defined fields in electronic claims.
☐All data elements are in defined fields in electronic clinical data such as clinical registry, nursing home MDS, and home health OASIS.
☒All data elements are in defined fields in a combination of electronic sources.
☐Some data elements are in defined fields in electronic sources.
☐No data elements are in defined fields in electronic sources.
☐Data are patient/family reported information; may be electronic or paper.

4.2.2 Path to Electronic Capture (NQF Measure Submission Form, Feasibility 3.03)

N/A

4.2.3 eCQM Feasibility (NQF Measure Submission Form, Feasibility 3.05)

N/A

4.3 Data Collection Strategy

4.3.1 Data Collection Strategy Difficulties (optional) (Measure Submission Form, Feasibility 3.06)

None identified.

4.3.2 Fees, Licensing, Other Requirements (NQF Measure Submission Form, Feasibility 3.07)

N/A

5. Usability and Use (NQF Usability and Use Criterion 4)

5.1 Use (NQF Measure evaluation criterion 4a)

5.1.1 Current and Planned Use (NQF Measure Submission Form, Use 4a.01 and 4a.02)

☐public reporting
☐public health or disease surveillance
☐payment program
☐regulatory and accreditation programs
☐professional certification or recognition program
☐quality improvement with external benchmarking to multiple organizations
☐quality improvement internal to a specific organization
☒not in use
☐use unknown

5.1.1.1 Reasons for Not Publicly Reporting or Use in Other Accountability Application (NQF Measure Submission Form, Use 4a.03)

The measure is undergoing initial endorsement review.

5.1.1.2 Plan for Implementation (NQF Measure Submission Form, Use 4a.04)

CMS will determine if/when to report this measure in a public reporting/payment program. One potential application for the measure is in the Quality Payment Program where it would be one of several optional measures that a group practice could select in their evaluation.

5.1.2 Feedback on the Measure by Those Being Measured or Others (NQF Measure Submission Form, Use 4a.05)

5.1.2.1 Technical Assistance Provided During Development or Implementation (NQF Measure Submission Form, Use 4a.06)

N/A

5.1.2.2 Technical Assistance with Results (NQF Measure Submission Form, Use 4a.06)

N/A

5.1.2.3 Feedback on Measure Performance and Implementation (NQF Measure Submission Form, Use 4a.07)

N/A

5.1.2.4 Feedback from Measured Entities (NQF Measure Submission Form, Use 4a.08)

N/A

5.1.2.5 Feedback from Other Users (NQF Measure Submission Form, Use 4a.09)

N/A

5.1.2.6 Consideration of Feedback (NQF Measure Submission Form, Use 4a.10)

N/A

5.2 Usability (NQF Measure evaluation criterion 4b)

5.2.1 Improvement (NQF Measure Submission Form, Usability 4b.01)

N/A

5.2.2 Unexpected Findings (NQF Measure Submission Form, Usability 4b.02)

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

5.2.3 Unexpected Benefits (NQF Measure Submission Form, Usability 4b.03)

N/A

6. Related and Competing Measures (NQF Related and Competing Criterion 5)

6.1 Relation to Other NQF-Endorsed Measures (NQF Measure evaluation criterion 5)

Are there related measures or competing measures?

☐yes
☒no

6.2 Harmonization (NQF Measure Submission Form, Related and Competing 5.04 and 5.04)

N/A

6.3 Competing Measures (NQF Measure Submission Form, Related and Competing 5.06)

N/A

Additional Information (NQF Measure Submission Form, Additional)

Appendix

Available in attached files.

Other Additional Information

Ad.1. Working Group/Expert Panel Involved in Measure Development

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Sumit Mohan, MD, MPH
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Dawn P. Edwards
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Geraldine Zingraf, DNP, MBA, RN, CNN, CCTC
Transplant Administrator, Edward Hines, Jr. VA Hospital

Sasha Couch
Patient, Renal Support Network

Measure Developer/Steward Updates and Ongoing Maintenance

Ad.2. First Year of Measure Release

2022

Ad.3. Month and Year of Most Recent Revision

01/2022

Ad.4. What is your frequency for review/update of this measure?

Annual

Ad.5. When is your next scheduled review/update for this measure?

4/2023

Ad.6. Copyright Statement

N/A

Ad.7. Disclaimers

N/A

Ad.8. Additional Information/Comments

N/A

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