Measure Justification Form

Project Title:

End-Stage Renal Disease Access to Kidney Transplantation Measure Development

Project Overview:

The Centers for Medicare & Medicaid Services (CMS) has contracted with the University of Michigan's Kidney Epidemiology and Cost Center (UM-KECC) to develop access to kidney transplantation measures for ESRD patients. The contract name is the ESRD Quality Measure Development, Maintenance, and Support contract. The contract number is HHSM-500-2013-13017I.

Date:

Information included is current on December 21, 2015.

Measure Name

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

Type of Measure

Importance

1a—Opportunity for Improvement

1a.1. This is a Measure of Process (kidney or kidney-pancreas transplant waitlist)

1a.2.—Linkage

1a.2.1 Rationale

1a.3.—Linkage

The intended objective of this measure is to increase access to kidney transplantation among patients on dialysis. Patients can receive a kidney transplant either from a living donor or a deceased donor. To access transplantation from a deceased donor, the patient must first be accepted on to the kidney transplant wait list. This measure assesses either a receipt of a living donor transplant, or placement on the kidney or kidney-pancreas transplant wait list, which is a necessary intermediate process prior to potential receipt of a deceased donor transplant. The process flow for the steps involved is diagrammed below:

Patients with ESRD are initiated on dialysis → Patients not already on the wait list are assessed for eligibility for transplant referral by a nephrologist at the dialysis facility→ Patients are referred to a transplant center for evaluation of candidacy for kidney or kidney-pancreas transplantation → Dialysis facility assists patient with completion of the transplant evaluation process and in 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 → Patients on the wait list have the potential to receive a deceased donor transplant if a compatible one becomes available → Increase in access to transplantation.

1a.3.1. Source of Systematic Review

Other systematic review and grading of the body of evidence

1a.4.—Clinical Practice Guideline Recommendation

1a.4.2. Specific Guideline

N/A

1a.4.3. Grade

N/A

1a.4.4. Grades and Associated Definitions

N/A

1a.4.5. Methodology Citation

N/A

1a.4.6. Quantity, Quality, and Consistency

N/A

1a.5.—United States Preventative Services Task Force Recommendation

1a.5.1. Recommendation Citation

N/A

1a.5.2. Specific Recommendation

N/A

1a.5.3. Grade

N/A

1a.5.4. Grades and Associated Definitions

N/A

1a.5.5. Methodology Citation

N/A

1a.6.—Other Systematic Review of the Body of Evidence

1a.6.1. Review Citation

Tonelli M, Wiebe N, Knoll G, et al. Systematic review: kidney transplantation compared with dialysis in clinically relevant outcomes. American Journal of Transplantation 2011 Oct; 11(10): 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.

1a.6.2. Methodology Citation

Downs and Black. J Epidemiol Community Health 1998; 52:377-384.

1a.7.—Findings from Systematic Review of Body of the Evidence Supporting the Measure

1a.7.1. Specifics Addressed in Evidence Review

The benefits of kidney transplantation over dialysis as a modality for renal replacement therapy for patients with end-stage renal disease are well established. Although no clinical trials comparing the two have ever been done due to ethical considerations, a large number of observational studies have been conducted demonstrating improved survival and quality of life with kidney transplantation. This body of work was most recently summarized in a comprehensive systematic review published in 2011. The review examined the outcomes of overall mortality, quality of life and cardiovascular events and hospitalizations. Studies examining outcomes comparing various dialysis modalities (including in-center hemodialysis, home hemodialysis and peritoneal dialysis) versus living or deceased donor transplantation were included. Many of the studies included comparisons of patients on dialysis who were waitlisted versus those who received a transplant as a means of reducing selection biases. All studies used either prospective and/or retrospective cohort designs.

1a.7.2. Grade

No formal grading was used by the authors of the systematic review. However, evaluation of the quality of the studies was performed (described in more detail in section 1a.7.6). The authors concluded based on the consistent beneficial effect noted on mortality for transplantation versus a range of dialysis modalities that kidney transplantation is the preferred modality of treatment for patients requiring renal replacement therapy.

1a.7.3. Grades and Associated Definitions

N/A

1a.7.4. Time Period

The review focused on studies published between 1973 and 2010, representing over 1.9 million patients.

1a.7.5. Number and Type of Study Designs

A total of 110 studies were included in the review, representing over 1.9 million patients. All studies were either retrospective and/or prospective cohort observational study designs. No randomized clinical trials were available for inclusion.

1a.7.6. Overall Quality of Evidence

The review authors evaluated the risk of bias for each included study using the system developed by Downs and Black. The system has a checklist of items for evaluating the risk of bias, such as study design (retrospective/prospective), contemporaneous control population, detailed description of study population and use of an adjusted model. Approximately 20-30% of the included studies were given a rating of the smallest risk of bias across the different items. Despite the risk of bias in a substantial portion of studies, there was a consistent finding of benefit for transplantation in terms of mortality, even among the subset of studies with the lowest risk of bias.

1a.7.7. Estimates of Benefit

Due to heterogeneity, results were not formally pooled. However, the majority of studies (76%) demonstrated a survival advantage for kidney transplantation. Among those studies with the best design for reducing selection bias, including multivariable adjustment and a comparison group consisting of waitlisted dialysis patients, 94% of tested comparisons demonstrated a lower mortality with transplantation (with hazard ratios ranging from 0.16-0.73). Similarly, the vast majority of studies demonstrated better quality of life scores on the SF-36 for kidney transplant patients versus those on dialysis.

1a.7.8. Benefits Over Harms

No harms were examined.

1a.7.9. Provide for Each New Study

More recent studies published after this review also confirm the survival benefits of kidney transplantation over dialysis and none substantively affect the conclusions of the systematic review [1,2,3,4,5,6,7,8].

1. Reese PP, Shults J, Bloom RD, et al. Functional Status, Time to Transplantation, and Survival Benefit of Kidney Transplantation Among Wait-Listed Candidates. Am J Kidney Dis. 2015 Jul 7. pii: S0272-6386(15)00844-6

   Abstract:

   BACKGROUND: In the context of an aging end-stage renal disease population with multiple comorbid conditions, transplantation professionals face challenges in evaluating the global health of patients awaiting kidney transplantation. Functional status might be useful for identifying which patients will derive a survival benefit from transplantation versus dialysis.

   STUDY DESIGN: Retrospective cohort study of wait-listed patients using data for functional status from a national dialysis provider linked to United Network for Organ Sharing registry data.

   SETTING & PARTICIPANTS: Adult kidney transplantation candidates added to the waiting list between 2000 and 2006.

   PREDICTOR: Physical Functioning scale of the Medical Outcomes Study 36-Item Short Form Health Survey, analyzed as a time-varying covariate.

   OUTCOMES: Kidney transplantation; survival benefit of transplantation versus remaining wait-listed.

MEASUREMENTS: We used multivariable Cox regression to assess the association between physical function with study outcomes. In survival benefit analyses, transplantation status was modeled as a time-varying covariate.

RESULTS: The cohort comprised 19,242 kidney transplantation candidates (median age, 51 years; 36% black race) receiving maintenance dialysis. Candidates in the lowest baseline Physical Functioning score quartile were more likely to be inactivated (adjusted HR vs highest quartile, 1.30; 95% CI, 1.21-1.39) and less likely to undergo transplantation (adjusted HR vs highest quartile, 0.64; 95% CI, 0.61-0.68). After transplantation, worse Physical Functioning score was associated with shorter 3-year survival (84% vs 92% for the lowest vs highest function quartiles). However, compared to dialysis, transplantation was associated with a statistically significant survival benefit by 9 months for patients in every function quartile.

LIMITATIONS: Functional status is self-reported.

CONCLUSIONS: Even patients with low function appear to live longer with kidney transplantation versus dialysis. For wait-listed patients, global health measures such as functional status may be more useful in counseling patients about the probability of transplantation than in identifying who will derive a survival benefit from it.

2. Lloveras J, Arcos E, Comas J, Crespo M, Pascual J. A paired survival analysis comparing hemodialysis and kidney transplantation from deceased elderly donors older than 65 years. Transplantation. 2015 May; 99(5):991-6.

Abstract:

BACKGROUND: Kidney transplantation from deceased donors aged 65 years or older is associated with suboptimal patient and graft survival. In large registries, survival is longer after kidney transplantation than when remaining on dialysis. However, whether recipients of these old grafts survive longer than their dialysis counterparts is unknown.

METHODS: We retrospectively assessed the outcomes of 5,230 recipients of first deceased donor grafts transplanted during the period of 1990 to 2010 in Catalonia, 915 of whom received grafts from donors 65 years or older. In a match-pair analysis, we aimed to pair each of 915 eligible cases with one control (1:1 ratio). Each pair had the same characteristics at the time of entering dialysis program: age, sex, primary renal disease, period of dialysis onset, and cardiovascular comorbidities. We found 823 pairs.

RESULTS: Patient survival of 823 recipients of elderly donors was significantly higher than that of their 823 matched dialysis waitlisted nontransplanted partners (91.6%, 74.5%, and 55.5% vs. 88.8%, 44.2%, and 18.1%, respectively at 1, 5, and 10 years; P<0.001). The probability of death after the first year was similar (8.1% transplant vs 10.3% dialysis; P=0.137); however, analyzing the whole period, the adjusted proportional risk of death was 2.66 (95% confidence interval, 2.21-3.20) times higher for patients remaining on dialysis than for transplanted patients (P<0.001).

CONCLUSION: Our study demonstrates that despite the fact that kidney transplantation from elderly deceased donors is associated with reduced graft and patient survival, their paired counterpart patients remaining on dialysis have a risk of death 2.66 times higher.

3. Schold JD, Buccini LD, Goldfarb DA, et al. Association between kidney transplant center performance and the survival benefit of transplantation versus dialysis. Clin J Am Soc Nephrol. 2014 Oct 7; 9(10):1773-80.

   Abstract:

   BACKGROUND AND OBJECTIVES: Despite the benefits of kidney transplantation, the total number of transplants performed in the United States has stagnated since 2006. Transplant center quality metrics have been associated with a decline in transplant volume among low-performing centers. There are concerns that regulatory oversight may lead to risk aversion and lack of transplantation growth.

   DESIGN, SETTING, PARTICIPANTS, & MEASUREMENTS: A retrospective cohort study of adults (age≥18 years) wait-listed for kidney transplantation in the United States from 2003 to 2010 using the Scientific Registry of Transplant Recipients was conducted. The primary aim was to investigate whether measured center performance modifies the survival benefit of transplantation versus dialysis. Center performance was on the basis of the most recent Scientific Registry of Transplant Recipients evaluation at the time that patients were placed on the waiting list. The primary outcome was the time-dependent adjusted hazard ratio of death compared with remaining on the transplant waiting list.

   RESULTS: Among 223,808 waitlisted patients, 59,199 and 32,764 patients received a deceased or living donor transplant, respectively. Median follow-up from listing was 43 months (25th percentile=25 months, 75th percentile=67 months), and there were 43,951 total patient deaths. Deceased donor transplantation was independently associated with lower mortality at each center performance level compared with remaining on the waiting list; adjusted hazard ratio was 0.24 (95% confidence interval, 0.21 to 0.27) among 11,972 patients listed at high-performing centers, adjusted hazard ratio was 0.32 (95% confidence interval, 0.31 to 0.33) among 203,797 patients listed at centers performing as expected, and adjusted hazard ratio was 0.40 (95% confidence interval, 0.35 to 0.45) among 8039 patients listed at low-performing centers. The survival benefit was significantly different by center performance (P value for interaction <0.001).

   CONCLUSIONS: Findings indicate that measured center performance modifies the survival benefit of kidney transplantation, but the benefit of transplantation remains highly significant even at centers with low measured quality. Policies that concurrently emphasize improved center performance with access to transplantation should be prioritized to improve ESRD population outcomes.

4. Tennankore KK, Kim SJ, Baer HJ, Chan CT. Survival and hospitalization for intensive home hemodialysis compared with kidney transplantation. J Am Soc Nephrol. 2014 Sep; 25(9):2113-20.

   Abstract:

   Canadian patients receiving intensive home hemodialysis (IHHD; ≥16 hours per week) have survival comparable to that of deceased donor kidney transplant recipients in the United States, but a comparison with Canadian kidney transplant recipients has not been conducted. We conducted a retrospective cohort study of consecutive, adult IHHD patients and kidney transplant recipients between 2000 and 2011 at a large Canadian tertiary care center. The primary outcome was time-to-treatment failure or death for IHHD patients compared with expanded criteria, standard criteria, and living donor recipients, and secondary outcomes included hospitalization rate. Treatment failure was defined as a permanent switch to an alternative dialysis modality for IHHD patients, and graft failure for transplant recipients. The cohort comprised 173 IHHD patients and 202 expanded criteria, 642 standard criteria, and 673 living donor recipients. There were 285 events in the primary analysis. Transplant recipients had a reduced risk of treatment failure/death compared with IHHD patients, with relative hazards of 0.45 (95% confidence interval [95% CI], 0.31 to 0.67) for living donor recipients, 0.39 (95% CI, 0.26 to 0.59) for standard criteria donor recipients, and 0.42 (95% CI, 0.26 to 0.67) for expanded criteria donor recipients. IHHD patients had a lower hospitalization rate in the first year of treatment compared with standard criteria donor recipients and in the first 3 months of treatment compared with living donor and expanded criteria donor recipients. In this cohort, kidney transplantation was associated with superior treatment and patient survival, but higher early rates of hospitalization, compared with IHHD.

5. Gill JS, Lan J, Dong J, et al. The survival benefit of kidney transplantation in obese patients. Am J Transplant. 2013 Aug; 13(8):2083-90.

   Abstract:

   Obese patients have a decreased risk of death on dialysis but an increased risk of death after transplantation, and may derive a lower survival benefit from transplantation. Using data from the United States between 1995 and 2007 and multivariate non-proportional hazards analyses we determined the relative risk of death in transplant recipients grouped by body mass index (BMI) compared to wait-listed candidates with the same BMI (n = 208 498). One year after transplantation the survival benefit of transplantation varied by BMI: Standard criteria donor transplantation was associated with a 48% reduction in the risk of death in patients with BMI ≥ 40 kg/m(2) but a ≥ 66%

reduction in patients with BMI < 40 kg/m2. Living donor transplantation was associated with ≥ 66% reduction in the risk of death in all BMI groups. In sub-group analyses, transplantation from any donor source was associated with a survival benefit in obese patients ≥ 50 years, and diabetic patients, but a survival benefit was not demonstrated in Black patients with BMI ≥ 40 kg/m(2). Although most obese patients selected for transplantation derive a survival benefit, the benefit is lower when BMI is ≥ 40 kg/m(2), and uncertain in Black patients with BMI ≥ 40 kg/m(2).

6. Ingsathit A, Kamanamool N, Thakkinstian A, Sumethkul V. Survival advantage of kidney transplantation over dialysis in patients with hepatitis C: a systematic review and meta-analysis.Transplantation. 2013 Apr 15; 95(7):943-8.

   Abstract:

   BACKGROUND: The clinical outcomes of hepatitis C infection in kidney transplantation and maintenance dialysis patients remain controversial. Here, we conducted a systematic review and meta-analysis that aimed at comparing 5-year mortality rates between waiting list and kidney transplantation patients with hepatitis C infections.

   METHODS: We searched Medline, EMBASE, and Scopus databases published since inception to June 2011 and found nine studies with 1734 patients who were eligible for pooling. Eligible studies were cohort studies that analyzed adult end-stage renal disease patients with hepatitis C virus infection and compared death rates between waiting list and kidney transplantation. The crude risk ratio of death along with its 95% confidence interval was estimated for each study. Data were independently extracted by two reviewers.

   RESULTS: The pooled risk ratio of death at 5 years by using a random-effect model was 2.19 (95% confidence interval, 1.50-3.20), which significantly favored the kidney transplantation when compared with the waiting list. There was evidence of heterogeneity of death rates across studies ($\chi(2) = 22.6$; df = 8; $P = 0.004$). From the metaregression model, age and male gender could be the source of heterogeneity or variation of treatment effects. A major cause of death in the waiting list was cardiovascular diseases, whereas infection was a major cause in the transplant group. There was no evidence of publication bias suggested by an Egger test.

   CONCLUSIONS: This systematic review suggested that hepatitis C virus-infected patients who remain on dialysis are at higher risk of death when compared with those who received kidney transplantations.

7. De Lima JJ, Gowdak LH, de Paula FJ, et al. Which patients are more likely to benefit from renal transplantation? Clin Transplant. 2012 Nov-Dec; 26(6):820-5.

   Abstract:

BACKGROUND: We evaluated whether the advantages conferred by renal transplantation encompass all individuals or whether they favor more specific groups of patients.

METHODS: One thousand and fifty-eight patients on the transplant waiting list and 270 receiving renal transplant were studied. End points were the composite incidence of CV events and death. Patients were followed up from date of placement on the list until transplantation, CV event, or death (dialysis patients), or from the date of transplantation, CV event, return to dialysis, or death (transplant patients).

RESULTS: Younger patients with no comorbidities had a lower incidence of CV events and death independently of the treatment modality (log-rank=0.0001). Renal transplantation was associated with better prognosis only in high-risk patients (p=0.003).

CONCLUSIONS: Age and comorbidities influenced the prevalence of CV complications and death independently of the treatment modality. A positive effect of renal transplantation was documented only in high-risk patients. These findings suggest that age and comorbidities should be considered indication for early transplantation even considering that, as a group, such patients have a shorter survival compared with low-risk individuals.

8. Wong G, Howard K, Chapman JR, et al. Comparative survival and economic benefits of deceased donor kidney transplantation and dialysis in people with varying ages and co-morbidities. PLoS One. 2012; 7(1):e29591.

Abstract:

BACKGROUND: Deceased donor kidneys for transplantation are in most countries allocated preferentially to recipients who have limited co-morbidities. Little is known about the incremental health and economic gain from transplanting those with co-morbidities compared to remaining on dialysis. The aim of our study is to estimate the average and incremental survival benefits and health care costs of listing and transplantation compared to dialysis among individuals with varying co-morbidities.

METHODS: A probabilistic Markov model was constructed, using current outcomes for patients with defined co-morbidities treated with either dialysis or transplantation, to compare the health and economic benefits of listing and transplantation with dialysis.

FINDINGS: Using the current waiting time for deceased donor transplantation, transplanting a potential recipient, with or without co-morbidities achieves survival gains of between 6 months and more than three life years compared to remaining on dialysis, with an average incremental cost-effectiveness ratio (ICER) of less than \$50,000/LYS, even among those with advanced age. Age at listing and the waiting time for transplantation are the most influential variables within the model. If there were an unlimited supply of organs and no waiting time, transplanting the younger and healthier individuals saves the most number of life years and is cost-saving, whereas transplanting the middle-age to older patients still achieves substantial incremental gains in life expectancy compared to being on dialysis.

CONCLUSIONS: Our modelled analyses suggest transplanting the younger and healthier individuals with end-stage kidney disease maximises survival gains and saves money. Listing and transplanting those with considerable co-morbidities is also cost-effective and achieves substantial survival gains compared with the dialysis alternative. Preferentially excluding the older and sicker individuals cannot be justified on utilitarian grounds.

1a.8.—Other Source of Evidence

N/A

1a.8.1. Process Used

N/A

1a.8.2. Citation

N/A

1b.—Evidence to Support Measure Focus

1b.1. Rationale

A measure focusing on the wait listing process is appropriate for improving access to kidney transplantation for several reasons. First, wait listing is a necessary step prior to potential receipt of a deceased donor kidney (receipt of a living donor kidney is also accounted for in the measure). Second, dialysis facilities exert substantial control over the process of waitlisting. This includes proper education of dialysis patients on the option for transplant, referral of appropriate patients to a transplant center for evaluation, assisting patients with completion of the transplant evaluation process, and optimizing the health and functional status of patients in order to increase their candidacy for transplant wait listing. These types of activities are included as part of the conditions for coverage for Medicare certification of ESRD dialysis facilities. Finally, wide regional variations in wait listing rates highlight substantial room for improvement for this process measure [1,2,3]. This measure additionally 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 facilities to waitlisting of patients to ensure early access to transplantation.

1. 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.

2. 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.

3. 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.

1b.2. Performance Scores

The Standardized Waitlist Ratio varies widely across facilities (see table 1 below), suggesting substantial opportunity for improvement. The mean value of SWR was 1.11.

Table 1. Mean standard deviation and quartiles of SWR (after exclusion of small facilities)

N	Mean	Standard Deviation	0% Min	25% Q1	50% Median	75% Q3	100% Max
5154	1.11	1.00	0.00	0.43	0.87	1.50	12.00

1b.3. Summary of Data Indicating Opportunity

N/A

1b.4. and 1b.5. Disparities

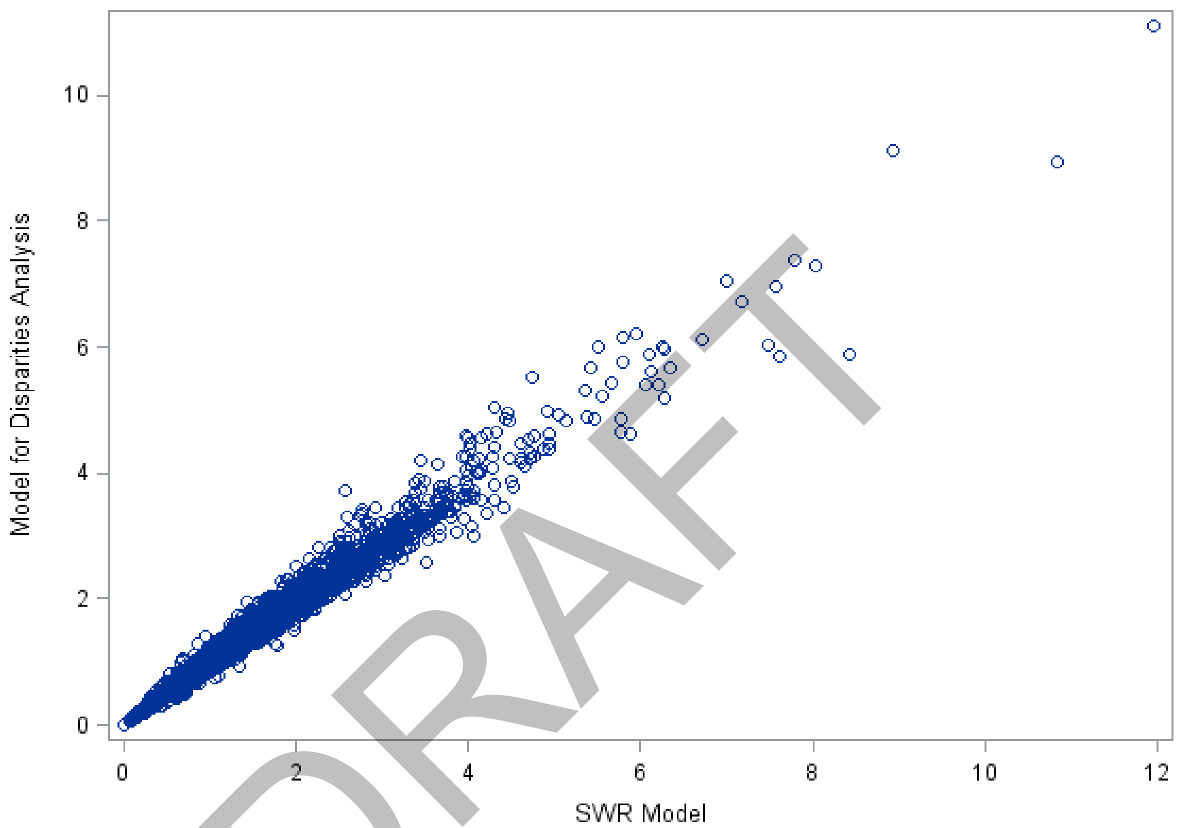
The table below shows the parameter estimates for the race, sex and ethnicity variables based on a model that included these variables along with original covariates. There is evidence of significant differences in measure results by sex, race and ethnicity. However, there is no clear biological rationale for differences in waitlisting on the basis of sex, race or ethnicity to justify a need for adjustment. Nevertheless, a model adjusting for these parameters is highly correlated with the original model (adjusted for age only), suggesting minimal impact on performance scores (see Figure 1 below).

Table 2. Estimates and p-values for race, sex and ethnicity

Parameter	Estimate	Standard Error	P value
Race			
White	reference		
Native American	-0.51	0.09	<.001
Asian	0.26	0.03	<.001
Black	-0.31	0.02	<.001
Other race	0.11	0.13	0.402
Sex			
Male	reference		
Female	-0.21	0.01	<.001
Ethnicity			
Hispanic	reference		
Non-Hispanic	0.05	0.02	0.011
Unknown	-0.96	0.20	<.001

Figure 1 shows the correlation of SWR between model described above and original model (adjusted for age only). The Spearman correlation is 0.99 (p-value<.001) indicating that the adjustment for sex, race and ethnicity generally has very little impact, relative to adjusting for age alone.

Figure 1. Scatter plot of SWR between two models



1c.—High Priority

1c.1. Demonstrated High-Priority Aspect of Health Care

Affects large numbers
A leading cause of morbidity/mortality

1c.3. Epidemiologic or Resource Use Data

The measure focuses on patients incident to dialysis. This represents nearly 120,000 patients each year in the United States with a mortality of roughly 25% within the first year of dialysis initiation.

1c.4. Citations

United States Renal Data System. 2015 USRDS annual data report: Epidemiology of kidney disease in the United States. National Institutes of Health, National Institute of Diabetes and Digestive and Kidney Diseases, Bethesda, MD, 2015.

1c.5. Patient-Reported Outcome Performance Measure (PRO-PM)

N/A

Scientific Acceptability

1.—Data Sample Description

1.1. What Type of Data was Used for Testing?

Administrative Claims

Clinical Database/Registry: CROWNWeb

Clinical database/registry

1.2. Identify the Specific Dataset

2011-2013 data derived from a combination of Medicare claims, CROWNWeb, and transplant registries (OPTN, SRTR)

1.3. What are the Dates of the Data Used in Testing?

Data from calendar years 2011 through 2013 were used for testing.

1.4. What Levels of Analysis Were Tested?

Hospital/Facility/Agency

1.5. How Many and Which Measured Entities Were Included in the Testing and Analysis?

Using data from 2011-2013, there were 5,154 facilities included in these analyses, after restricting to facilities that had >11 eligible patients.

1.6. How Many and Which Patients Were Included in the Testing and Analysis?

In 2011-2013, there were 210,562 patients in total. Among those patients over 2011-2013, the average age was 57 years, 41.6% of patient were female, 63.4% were white, 30.6 % were black, 0.2% were other, 17.6% were Hispanic.

1.7. Sample Differences, if Applicable

N/A

2a.2—Reliability Testing

2a2.1. Level of Reliability Testing

Performance measure score (e.g., signal-to-noise analysis)

2a2.2. Method of Reliability Testing

See Appendix C.

2a2.3. Statistical Results from Reliability Testing

The IUR value is 0.63 for 5,154 facilities. Facilities with <11 eligible patients were excluded from this calculation.

2a2.4. Interpretation

This value of IUR indicates that about two-thirds of the variation in the SWR can be attributed to the between-facility differences (signal) and about one-third to within-facility variation (noise). This value of IUR implies a moderate degree of reliability.

2b2—Validity Testing

2b2.1. Level of Validity Testing

Performance measure score

Empirical validity testing

2b2.2. Method of Validity Testing

The measure has face validity given the process of waitlisting is a necessary step to deceased donor transplantation. In addition, the waitlisting measure was developed with the majority approval of a Technical Expert Panel. Finally, Spearman correlation of facility ranking with respect to the measure and the Standardized Transplant Ratio (STR) is reported. The STR is the ratio of the actual number of first transplants to the expected number of first transplants for the facility, given the age composition of the facility's patients. There are 4,375 facilities available for comparison.

2b2.3. Statistical Results from Validity Testing

The Spearman correlation coefficient between facility SWR and STR was highly significant: rho=0.53, $p<.0001$

2b2.4. Interpretation

SWR is positively correlated with STR, suggesting that facilities with higher waitlisting rates also have higher transplant rates.

2b3—Exclusions Analysis

2b3.1. Method of Testing Exclusions

In order to see the differences with and without excluding nursing home patients, numbers of patients before and after exclusion were compared (Table 3). At facility level, histogram of percentage of patient excluded and number of patients excluded each year were shown (Figure 2 and Figure 3). Also, quantiles of crude waitlist rates before and after exclusion were calculated.

2b3.2. Statistical Results From Testing Exclusions

Table 3. Number of patients before and after excluding SNF patients

	# patients (Before exclusion)	# patients (After exclusion)	Percentage of SNF patients
2011	74353	68602	7.7%
2012	76943	71230	7.4%
2013	79670	70730	11.2%

Figure 2. Histogram of percentage of SNF patients at facility level

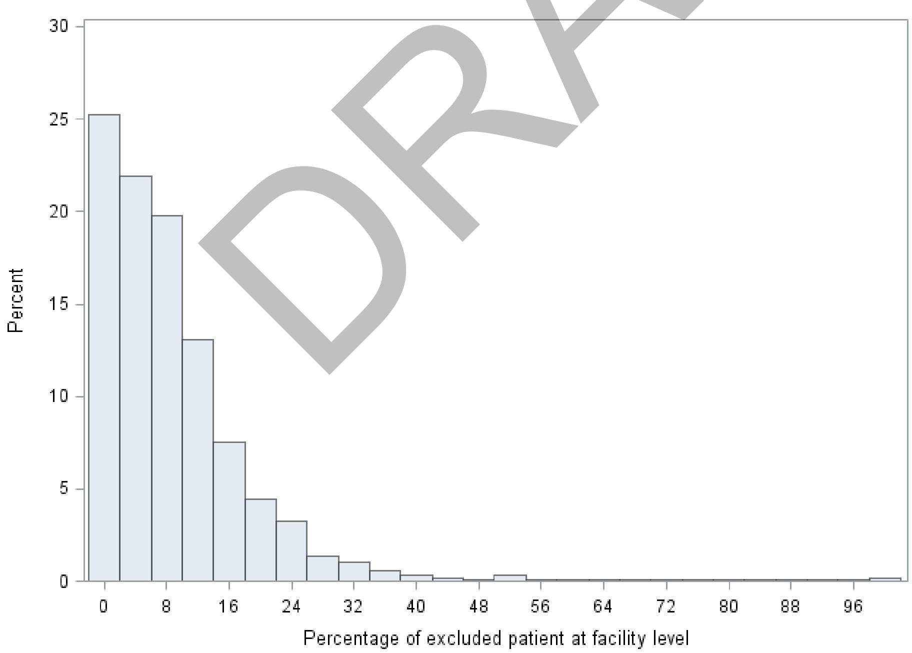


Figure 3. Distribution of Excluded Patients at Facility Level for 2011-2013

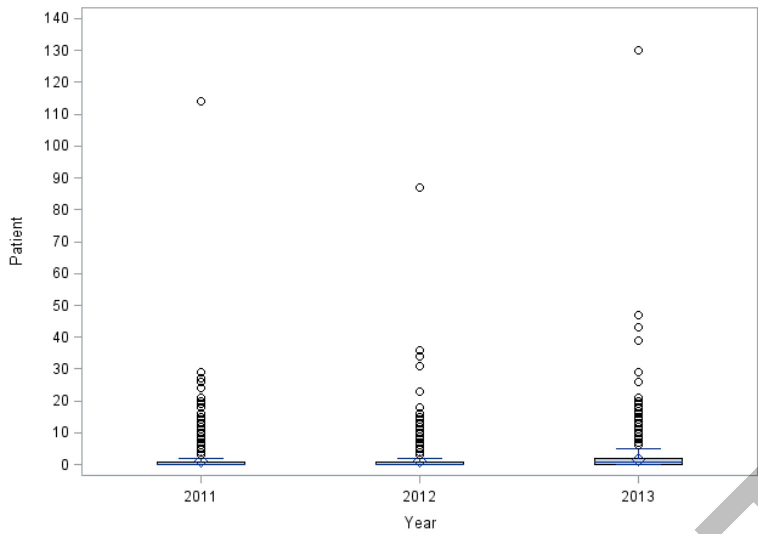


Table 4. Quantiles of crude waitlist rates before and after excluding SNF patients

	Mean (Std)	Q1 (25%)	Q2 (50%)	Q3 (75%)	Max (100%)
Before exclusion	0.11 (0.11)	0.04	0.09	0.16	1.00
After exclusion	0.12 (0.10)	0.05	0.10	0.17	0.97

2b3.3. Interpretation

Figures 2 and 3 reveal substantial variation in the percent and number of excluded patients across facilities, supporting the need for exclusion to prevent distortion in performance results across facilities.

2b4—Risk Adjustment or Stratification

2b4.1. Method of controlling for differences

Statistical risk model with age (knots at 12, 18 and 64) as the risk factors.

2b4.2. Rationale why Risk Adjustment is not Needed

N/A

2b4.3. Conceptual, Clinical, and Statistical Methods

Age adjustment was deemed necessary on clinical grounds. Although age alone is not a contraindication to transplantation, older patients are likely to have more comorbidities and be generally more frail thus making them potentially less suitable candidates for transplantation and therefore some may be appropriately excluded from waitlisting for transplantation. This may affect waitlisting rates for facilities with a substantially older age composition than the average.

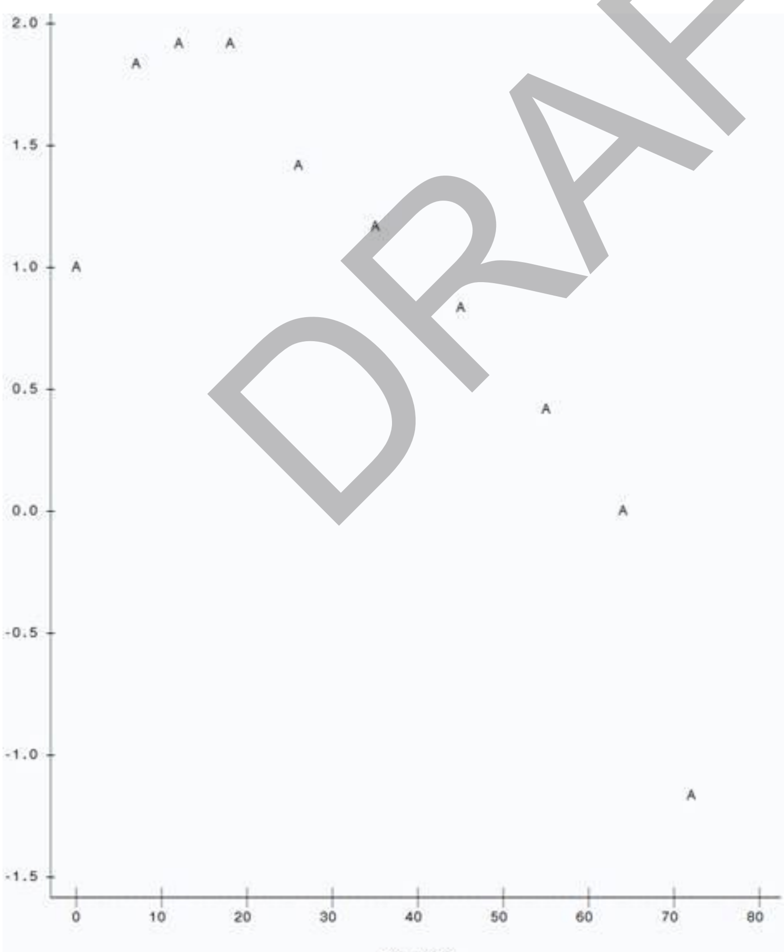
2b4.4. Statistical Results

Table 5. Coefficients and p-value in final model (note: $a_+=\max(a,0)$)

Covariate	Coefficient	p-value
Age	0.10	<.001
$(age-12)_+$	-0.18	<.001
$(age-18)_+$	0.04	0.008
$(age-64)_+$	-0.11	<.001

2b4.5. Method Used to Develop the Statistical Model or Stratification Approach

Figure 4. Plot of age trend (linear predictor versus median of age)



2b4.6. Statistical Risk Model Discrimination Statistics (e.g., c-statistic, R^2)

The c-index is 0.74 for our model, which suggests relatively good discrimination ability (e.g., differentiating high from low risk patients) of the risk model. In particular, among all pairs of patients where the ordering of time-to-event is known, the model correctly predicted the ordering 74% of the time.

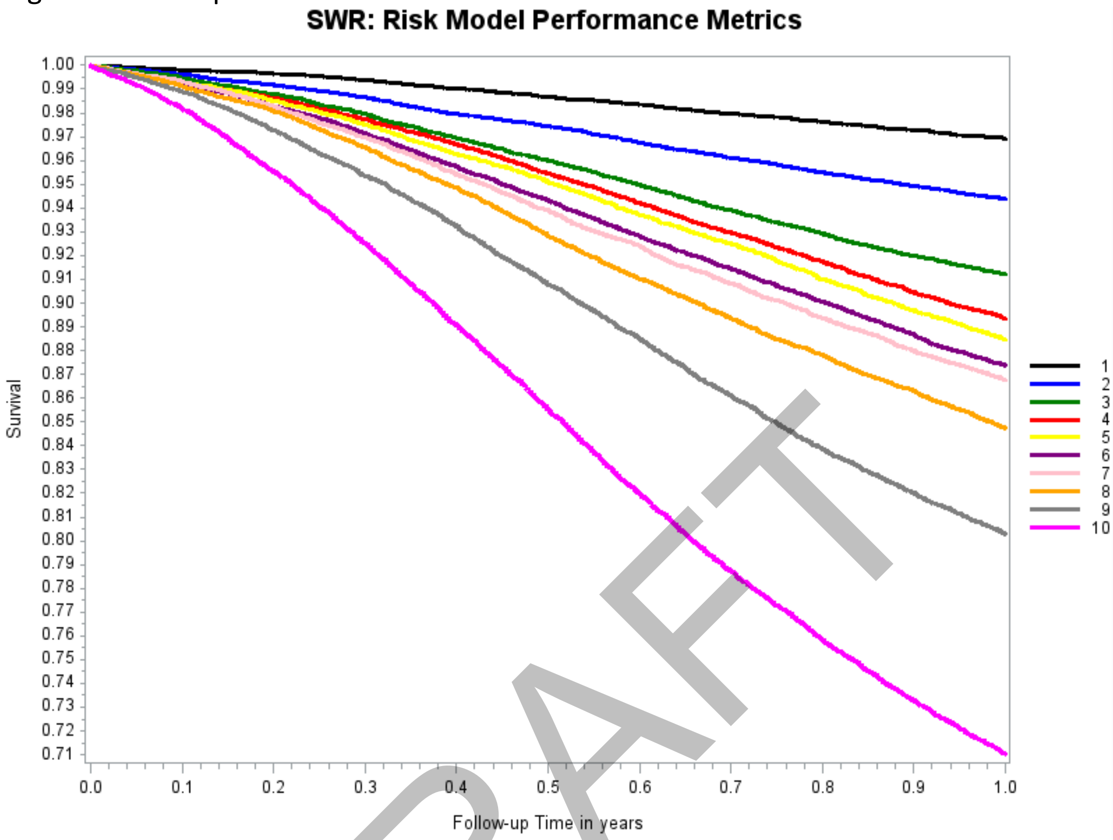
2b4.7. Statistical Risk Model Calibration Statistics (e.g., Hosmer-Lemeshow statistic)

Table 6. Comparison of numbers of observed and expected waitlist events

Decile	Number of Patients	Observed Event	Expected event	(Obs-Exp)/Exp
1	22345	584	588.64	-0.0079
2	22906	1124	994.95	0.1297
3	20489	1601	1425.05	0.12347
4	21065	2023	2016.08	0.00343
5	17484	1837	1844.83	-0.0042
6	22981	2677	2684.18	-0.0027
7	18719	2311	2484.41	-0.0698
8	22095	3169	3358.74	-0.0565
9	21037	3957	3920.87	0.00922
10	21441	6007	5972.25	0.00582

2b4.8. Statistical Risk Model Calibration—Risk decile plots or calibration curves

Figure 5: Decile plots for SWR



2b4.9. Results of Risk stratification Analysis

N/A

2b4.10. Interpretation

The comparison of observed to predicted events across each decile (Table 6) shows minimal differences, suggesting good calibration of the model. In addition, the Kaplan-Meier plots by decile (Figure 5) reveal that the time-to-event probabilities by risk decile are sequenced in consistently with the probability orderings based on the Cox model. Note that this is not merely a by-product of the model itself, but evidence of accurate risk discrimination and calibration.

2b4.11. Optional Additional Testing for Risk Adjustment

2b5—Identification of statistically significant and clinically meaningful differences

2b5.1. Method for determining

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

2b5.2. Statistical Results

Table 7. Number and percentage of facilities by classification of the SWR.

Better than expected	**As expected**	**Worse than expected**	**Total**
528 (10.2%)	4274 (82.9%)	352 (6.8%)	5154

2b5.3. Interpretation

Most facilities (82.9%) had a SWR that was "As expected". Approximately 10.2% of facilities had a SWR that was "Better than expected", while nearly 6.8% had "Worse than expected". This analysis demonstrates both practical and statistically significant differences in performance across facilities based on their proportion of patients placed on the transplant waitlist.

2b6—Comparability of performance scores

2b6.1. Method of testing conducted to demonstrate comparability

N/A

2b6.2. Statistical Results

N/A

2b6.3. Interpretation

N/A

Feasibility

3a.1. How are the data elements needed to compute measure scores generated

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

3b.1. Are the data elements needed for the measure as specified available electronically

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

3b.3. If this is an eMeasure, provide a summary of the feasibility assessment

N/A

3c.1. Describe what you have learned or modified as a result of testing

N/A

3c.2. Describe any fees, licensing, or other requirements

N/A

Usability and Use

4.1—Current and Planned Use

Use	Planned	Current	For current use, provide Program Name and URL
a. Public Reporting	X		
b. Public Health/Disease Surveillance			
c. Payment Program	X		
d. Regulatory and Accreditation Programs			
e. Professional Certification or Recognition Program			
f. Quality Improvement with Benchmarking (external benchmarking to multiple organizations)			
g. Quality Improvement (Internal to the specific organization)			
h. Not in use			

4a.1. Program, sponsor, purpose, geographic area, accountable entities, patients

N/A

4a.2. If not publicly reported or used for accountability, reasons

Measure is currently under development.

4a.3. If not, provide a credible plan for implementation

CMS will determine if and when the measure will be implemented in a CMS program.

4b.1. Progress on improvement

N/A

4b.2. If no improvement was demonstrated, what are the reasons

The measure is not yet implemented in a public report program, so improvement could not be evaluated. CMS currently anticipates implementation of the Standardized Waitlist Ratio (SWR). Once implemented, facility performance on the measure can be evaluated to determine if the measure has supported and detected quality improvement in promoting waitlisting for the incident population.

Unintended Negative Consequences

4c.1. Were any unintended negative consequences to individuals or populations identified during testing, OR has evidence of unintended negative consequences to individuals or populations been reported since implementation? If so, identify the negative unintended consequences and describe how benefits outweigh them or actions taken to mitigate them.

We do not anticipate any harm or unintended consequences to patients as a result of this measure.

Related and Competing Measures

5—Relation to Other NQF-Endorsed Measures

5.1a. The measure titles and NQF numbers are listed here

None

5.1b. If the measures are not NQF-endorsed, indicate the measure title

None

5a—Harmonization

5a.1. Are the measure specifications completely harmonized

N/A

5a.2. If not completely harmonized, identify the differences rationale, and impact

N/A

5b—Competing measures
5b.1 Describe why this measure is superior to competing measures

N/A

Additional Information

Co.1.—Measure Steward Point of Contact
Co.1.1. Organization
Centers for Medicare & Medicaid Services

Co.1.2. First Name
Corette

Co.1.3. Last Name
Byrd

Co.1.4. Email Address
corette.byrd@cms.hhs.gov

Co.1.5. Phone Number

Co.2.—Developer Point of Contact (indicate if same as Measure Steward Point of Contact
Co.2.1. Organization
University of Michigan Kidney Epidemiology and Cost Center

Co.2.2. First Name
Jennifer

Co.2.3. Last Name
Sardone

Co.2.4. Email Address
jmsto@med.umich.edu

Co.2.5. Phone Number

Ad.1. Workgroup/Expert Panel Involved in Measure Development
According to the CMS Measure Management System Blueprint, TEPs are advisory to the measure contractor. In this advisory role, the primary duty of the TEP is to suggest

candidate measures and related specifications, review any existing measures, and determine if there is sufficient evidence to support the proposed candidate measures.

Stephen Pastan, MD
Associate Professor of Medicine, School of Medicine
Medical Director of Kidney and Pancreas Transplant Program, Emory Transplant Center
Emory University
Atlanta, GA

Amy Waterman, PhD
Associate Professor of Michigan, Division of Nephrology
Director of the Transplant Research and Education Center (TREC)
David Geffen School of Medicine
University of California, Los Angeles
Los Angeles, CA

Todd Pesavento, MD
Professor of Medicine, Department of Medicine
Medical Director of Kidney and Pancreas Transplantation
Comprehensive Transplant Center
Ohio State University
Columbus, OH

Sandra Amaral, MD, MHS
Assistant Professor, Division of Nephrology, Department of Pediatrics
Director of the Kidney Transplant Program, Children's Hospital of Philadelphia
Senior Scholar, Center for Clinical Epidemiology and Biostatistics, Perelman School of Medicine University of Pennsylvania
Philadelphia, PA

Ranjan Chanda, MD, MPH
Medical Director, Centennial Kidney Transplant Center
Partner, Nephrology Associates
Nashville, TN

Mary Beth Callahan, ACSW, LCSW
Senior Social Worker
Dallas Transplant Institute

Dallas, TX

Duane Dunn, MSW
National Director of Social Work Services
DaVita Healthcare Partners Inc.
Columbia, SC

Linda Wright, DrNP, RN, CNN, CCTC
American Nephrology Nurses Association
Kidney and Pancreas Transplant Coordinator, Certified Nephrology Nurse
Thomas Jefferson University Hospital
Philadelphia, PA

Robert Teaster, RN, MBA, CPTC, CPT
Administrator for Transplant Services
University of Virginia Medical Center
Charlottesville, VA

Chris Elrod, CCHT
Chief Technician/Bio Med
Dialysis Clinic, Inc.

Nancy Scott
President
Dialysis Patient Citizens Education Center
Washington, D.C.

Ad.2. Year the Measure Was First Released
2015
Ad.3. Month and Year of Most Recent Revision
December 2015
Ad.4. What is your frequency for review/update of this measure?
Annually
Ad.5. When is your next scheduled review/update for this measure?
TBD
Ad.6. Copyright Statement
N/A
Ad.7. Disclaimers
N/A
Ad.8. Additional Information/Comments
N/A

Appendix C (SWR)

2a2.2. Method of Reliability Testing

The reliability of the Standardized Waitlist Ratio (SWR) was assessed using data among ESRD dialysis patients during 2010-2013. If the measure were a simple average across individuals in the facility, the usual approach for determining measure reliability would be a one-way analysis of variance (ANOVA), in which the between and within facility variation in the measure is determined. The inter-unit reliability (IUR) measures the proportion of the total variation of a measure that is attributable to the between-facility variation.

The SWR, however, is not a simple average and we instead estimate the IUR using a bootstrap approach, which uses a resampling scheme to estimate the within facility variation that cannot be directly estimated by ANOVA. A small IUR (near 0) reveals that most of the variation of the measures between facilities is driven by random noise, indicating the measure would not be a good characterization of the differences among facilities, whereas a large IUR (near 1) indicates that most of the variation between facilities is due to the real difference between facilities.

Here we describe our approach to calculating IUR. Let $T_1,\ldots,T_N$ be the SWR for these facilities. Within each facility, select at random and with replacement B (say 100) bootstrap samples. That is, if the ith facility has n_i subjects, randomly draw with replacement n_i subjects from those in the same facility, find their corresponding SWR$_i$ and repeat the process B times. Thus, for the ith facility, we have bootstrapped SWRs of $T^*_{i1},\ldots,$ T^*_{i200}. Let S_i^* be the sample variance of this bootstrap sample. From this it can be seen that

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

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

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

where

$$\bar{T} = \sum n_i T_i / \sum n_i$$

is the weighted mean of the observed SWR and

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

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

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

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