Measure Information 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 October 25, 2017

Measure Name

Percentage of Prevalent Patients Waitlisted (PPPW)

Descriptive Information
Measure Name (Measure Title De.2.)
Percentage of Prevalent Patients Waitlisted (PPPW)

Measure Type De.1.
Process

Brief Description of Measure De.3.
This measure tracks the percentage of patients at each dialysis facility who were on the kidney or kidney-pancreas transplant waitlist. Results are averaged across patients prevalent on the last day of each month during the reporting year.

If Paired or Grouped De.4.
N/A

Measure Specifications

Measure-specific Web Page S.1.
N/A

If This Is an eMeasure S.2a.
N/A

Data Dictionary, Code Table, or Value Sets S.2b.
See appendix

For Endorsement Maintenance S.3.1 and S.3.2
N/A

Numerator Statement S.4.
Number of patient months in which the patient at the dialysis facility is on the kidney or kidney-

pancreas transplant waitlist as of the last day of each month during the reporting year.

Numerator Details S.5.
To be included in the numerator for a particular month, the patient must be on the kidney or kidney-pancreas transplant waitlist as of the last day of the month during the reporting year.

Denominator Statement S.6.
All patient-months for patients who are under the age of 75 on the last day of each month and who are assigned to the dialysis facility according to each patient's treatment history as of the last day of each month during the reporting year.

Denominator Details S.7.
A treatment history file is the data source for the denominator calculation used for the analyses supporting this submission. This file provides a complete history of the status, location, and dialysis treatment modality of an ESRD patient from the date of the first ESRD service until the patient dies or the data collection cutoff date is reached. For each patient, a new record is created each time he/she changes facility or treatment modality. Each record represents a time period associated with a specific modality and dialysis facility.
CROWNWeb is the primary basis for placing patients at dialysis facilities and dialysis claims are used as an additional source. Information regarding first ESRD service date, death, and transplant is obtained from CROWNWeb (including the CMS Medical Evidence Form (Form CMS-2728) and the Death Notification Form (Form CMS-2746)) and Medicare claims, as well as the Organ Procurement and Transplant Network (OPTN) and the Social Security Death Master File.
The model is currently age-adjusted, with age updated each month.

Denominator Exclusion (NQF Includes "Exception" in the "Exclusion" Field) S.8.
Exclusions that are implicit in the denominator include:

- Patients 75 years of age and older on the last day of each month during the reporting year.

In addition, patients who were admitted to a skilled nursing facility (SNF) or hospice during the month of evaluation were excluded from that month.
Denominator Exclusion Details (NQF Includes "Exception" in the "Exclusion" Field) S.9.
The Nursing Home Minimum Dataset and the Questions 17u and 22 on CMS Medical Evidence Form are used to identify patients in skilled nursing facilities. For hospice patients, a separate CMS file that contains final action claims submitted by Hospice providers was used to determine the hospice status.

Stratification Details/Variables S.10.
N/A

Risk Adjustment Type S.11.
The Percentage of Prevalent Patients Waitlisted (PPPW) measure is a directly standardized percentage, in the sense that each facility's percentage waitlisted is adjusted to the national age distribution (with 'national' here referring to all-facilities-combined). The PPPW for facility j is an estimate of what the facility's percentage of prevalent patients would equal if the facility's patient mix was equal to that of the nation as a whole. For each facility, we test the null hypothesis H_0: $PPPW_j = PPPW$, where $PPPW$ (absent the facility subscript) equals the average of the $PPPW_j$'s across all facilities.

We assume a logistic regression model for the probability that a prevalent patient is wait-listed. Consider patient *i* at facility *j* during calendar month *k*; we set the response variate to Y_{ijk} =1 if the patient is on the wait list and Y_{ijk} 0 if not. The model is adjusted for age,

$$\text{logit}(p_{\text{ijk}}) = \alpha_{\text{j}} + \beta A_{\text{ij}},$$

coded as a linear spline with empirically determined knots at ages 15, 55 and 70. As such, the only factors in the logistic model are age and i and the facility indicators. The model is fitted using Generalized Estimating Equations (GEE; Liang and Zeger, 1986) in order to account for the correlation within-patient across months.

With over 6,000 facilities, it is difficult to estimate all parameters (i.e., including the facility indicators) simultaneously. Therefore, we break the fitting process into stages. At the first stage, we estimate the β vector by averaging 10 subgroups of approximately 600 facilities each. At the second stage, we then estimate the α_{j} (j=1, .., 6000) by fitting facility-specific intercept-only GEE models, with the linear predictor from the first stage, $\beta A_{\text{ij,}}$ serving as an offset. Per well-established GEE results (e.g., Liang and Zeger, 1986), the estimator of α_{j} is consistent for its target value, and follows a Normal distribution with standard error given by the robust 'sandwich' estimator computed via GEE. We can then compute $PPPW_j$ for each facility *j* as follows:

$$PPPW_j = \sum_i \sum_l \sum_k \; exp(a_{\text{j}}+ \beta A_{\text{il}}) \,/\, \{1 + exp(a_{\text{j}} + \beta A_{\text{il}})\}. \,/\, \text{n},$$

where *n* = total number of patient-months included in the overall study sample. The standard error of $PPPW_j$ is estimated through the Delta method; i.e., $SE(PPPW_j)=d_j \; x \; SE(a_j)$, where $d_j = \sum_i \sum_l \sum_k \; exp(a_{\text{j}}+ \beta A_{\text{il}}) \,/\, \{1 + exp(a_{\text{j}} + \beta A_{\text{il}})\}^2 \,/\, \text{n}$.

We then carry out a two-sided Wald test (0.05 significance level) that $PPPW_j=PPPW$, where *PPPW* equals the national average percentage waitlisted. Note that Wald the test is based on the logit of $PPPW_j$, which is much more likely to follow a Normal distribution than $PPPW_j$ itself, due to the symmetry and lack of range restrictions of the transformed version.

Type of Score S.12.
Rate/Proportion

Interpretation of Score S.13.
Better quality = higher score

Calculation Algorithm/Measure Logic S.14.
See appendix

Sampling S.15.
N/A

Survey/Patient-Reported Data S.16.
N/A

Data Source S.17.
Administrative Claims
Electronic Clinical Data

Data Source or Collection Instrument S.18.
CROWNWeb is the primary data source we used for denominator, risk adjustment (age) and exclusion of patients older than 75 year-old (see information provided under "denominator details"). Organ Procurement and Transplant Network (OPTN) is the data source for numerator (waitlisting). The Nursing Home Minimum Dataset and Questions 17u and 22 on the CMS Medical Evidence Form are used to identify SNF patients. A separate CMS file that contains final action claims submitted by Hospice providers was used to determine the hospice status.

Data Source or Collection Instrument (Reference) S.19.
N/A

Level of Analysis S.20.
Facility

Care Setting S.21.
Dialysis Facility

Composite Performance Measure S.22.
N/A

Appendix: Data Dictionary and Flowchart

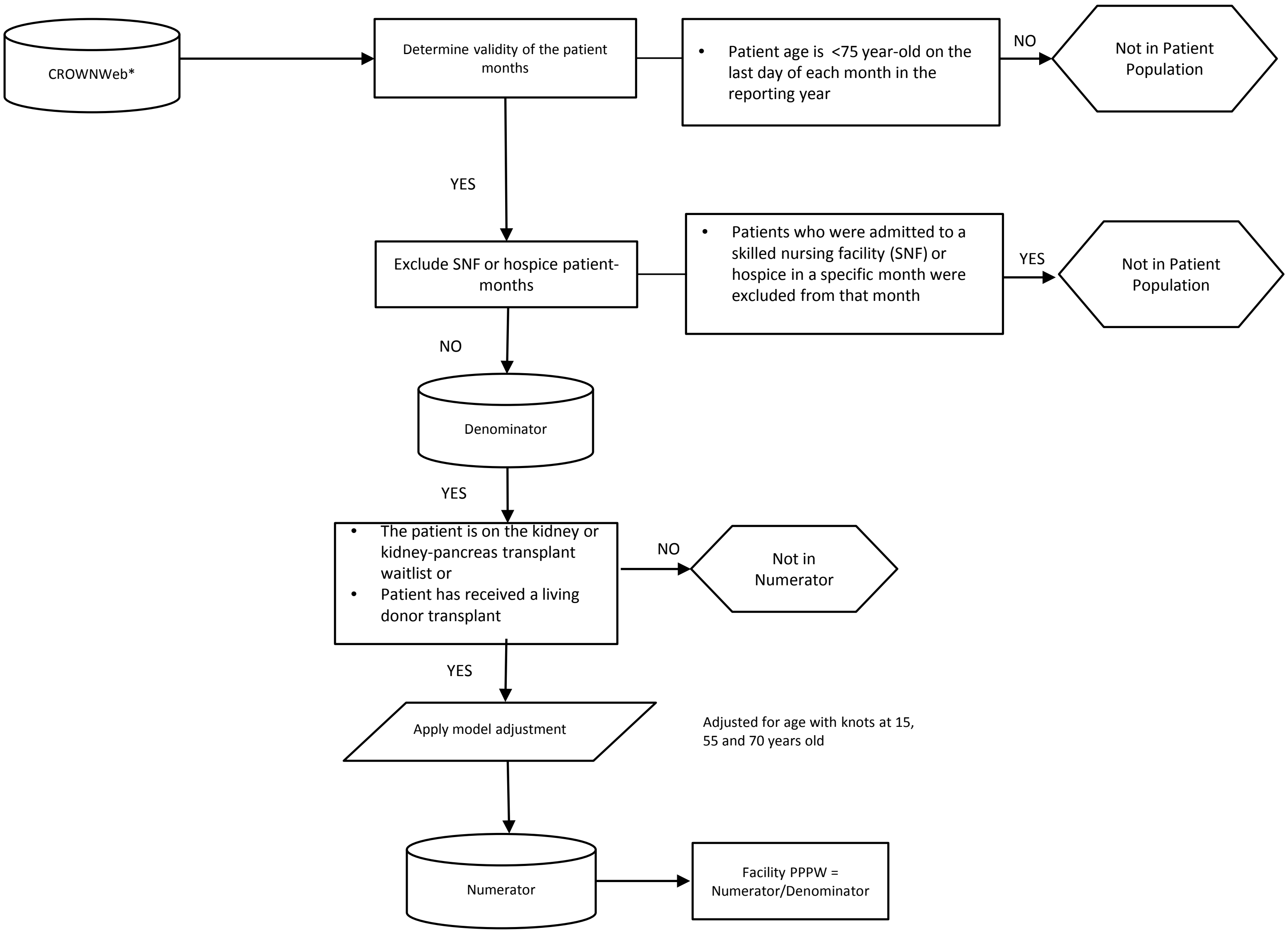
Variable	Primary Data Source
Facility CCN #	CMS data sources*1
Reporting year and month	CROWNWeb
Waitlist status	Organ Procurement and Transplant Network (OPTN)
Date of Birth	CMS data sources*1
Date of First ESRD	Medical Evidence Form (CMS-2728)
Age at the first day of reporting month	CMS data sources*1
Heart disease	Medical Evidence Form (CMS-2728)
Inability to ambulate	Medical Evidence Form (CMS-2728)
Chronic obstructive pulmonary disease	Medical Evidence Form (CMS-2728)
Inability to transfer	Medical Evidence Form (CMS-2728)
Malignant neoplasm, Cancer	Medical Evidence Form (CMS-2728)
Peripheral vascular disease	Medical Evidence Form (CMS-2728)
Cerebrovascular disease, CVA, TIA	Medical Evidence Form (CMS-2728)
Alcohol dependence	Medical Evidence Form (CMS-2728)
Drug dependence	Medical Evidence Form (CMS-2728)
Amputation	Medical Evidence Form (CMS-2728)
Needs assistance with daily activities	Medical Evidence Form (CMS-2728)
Nursing home status*2	Medical Evidence Form (Form CMS-2728) Question 17u and 22
Nursing home status on the first service date *2	CMS Long Term Care Minimum Data Set (MDS)
Hospice status on the first service date *2	CMS Hospice file

*1. Multiple data sources include CMS Consolidated Renal Operations in a Web-enabled Network (CROWNWeb), the CMS Annual Facility Survey (Form CMS-2744), Medicare dialysis and hospital payment records, the CMS Medical Evidence Form (Form CMS-2728), transplant data from the Organ Procurement and Transplant Network (OPTN), the Death Notification Form (Form CMS-2746), the Nursing Home Minimum Dataset, the Quality Improvement Evaluation System (QIES) Workbench, which includes data from the Certification and Survey Provider Enhanced Report System (CASPER), the Dialysis Facility Compare (DFC) and the Social Security Death Master File.

Unique patients are identified byusing a combination of SSN, first name, surname, gender, Medicare claim number and birth date. A matching process is performed to ensure that minor typos and misspellings do not cause a patient record to fall out of their history. The matching process is able to successfully match 99.5% of patients. The remaining patients have incomplete or incorrect data that does not allow them to be matched.

*2. Exclusion factors

Percentage of Prevalent Patients Waitlisted (PPPW)



*Multiple data sources include CMS Consolidated Renal Operations in a Web-enabled Network (CROWNWeb), the CMS Annual Facility Survey (Form CMS-2744), Medicare dialysis and hospital payment records, the CMS Medical Evidence Form (Form CMS-2728), transplant data from the Organ Procurement and Transplant Network (OPTN), the Death Notification Form (Form CMS-2746), the Dialysis Facility Compare (DFC) and the Social Security Death Master File.

MEASURE JUSTIFICATION FORM

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Measure Name: Title: Percentage of Prevalent Patients Waitlisted (PPPW)

Type of Measure: Process

Importance

1a—Opportunity for Improvement 1a.1.
This is a Measure of 1a.2.—Linkage
Process: kidney or kidney-pancreas transplant waitlisting

1a.2.1 Rationale
N/A

1a.3.—Linkage
The intended objective of this measure is to increase access to kidney transplantation among patients on dialysis. To access transplantation from a deceased donor, the patient must first be accepted on to the kidney transplant wait list. This measure assesses ongoing placement on the kidney or kidney-pancreas transplant wait list among prevalent dialysis patients, 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 → Dialysis facility helps patient maintain status on the wait list through involvement in ongoing evaluation activities and by optimizing health and functional status→ 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 (e.g., Cochrane Collaboration, AHRQ Evidence
Practice Center)

1a.4.—Clinical Practice Guideline Recommendation
1a.4.1. Guideline Citation
1a.4.2. Specific Guideline
1a.4.3. Grade
1a.4.4. Grades and Associated Definitions
1a.4.5. Methodology Citation
1a.4.6. Quantity, Quality, and Consistency

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

1a.5.1. Recommendation Citation
1a.5.2. Specific Recommendation
1a.5.3. Grade
1a.5.4. Grades and Associated Definitions
1a.5.5. Methodology Citation

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
1973-2010

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
1a.8.1. Process Used
1a.8.2. Citation

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. 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. In addition, dialysis facilities can also help maintain patients on the wait list through assistance with ongoing evaluation activities and by optimizing health and functional status. Finally, wide regional variations in wait listing rates highlight substantial room for improvement for this process measure [1,2,3]. This measure focuses specifically on the prevalent dialysis population, examining waitlisting status monthly for each patient. This allows evaluation and encouragement of ongoing waitlisting of patients beyond the first year of dialysis initiation who have not yet been listed. Patients may not be ready, either psychologically or due to their health status, to consider transplantation early after initiation of dialysis and many choose to undergo evaluation for transplantation only after years on dialysis. In addition, as this measure assesses monthly waitlisting status of patients, it also evaluates and encourages maintenance of patients on the waitlist. This is an important area to which dialysis facilities can contribute through ensuring patients remain healthy, and complete any ongoing testing activities required to remain on the wait list.

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 Percentage of Prevalent Patients Waitlisted (PPPW) varies considerably across facilities (see table 1 below). The mean value of PPPW was 0.21.

Table 1. Mean standard deviation and quartiles of PPPW

Mean	Standard Deviation	0% Min	25% Q1	50% Median	75% Q3	100% Max
0.21	0.11	0.00	0.12	0.19	0.27	0.78

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.

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

Parameter	Estimate	P value
Race		
White	reference	
Native American	-0.31	<.001
Asian	0.38	<.001
Black	-0.08	<.001
Other race	-0.01	0.93
Sex		
Male	reference	
Female	-0.08	<.001
Ethnicity		
Hispanic	reference	
Non-Hispanic/ Unknown	-0.04	0.01

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 prevalent patients on dialysis. This represents over 400,000 patients in the United States with a mortality of roughly 17% per year.

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. 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

1.2 Identify the Specific Dataset
2016 data derived from a combination of Medicare claims, CROWNWeb, Nursing Home Minimum Data Set, transplant registries (OPTN, SRTR), and CMS Medical Evidence Form (CMS Form-2728).

1.3 What are the Dates of the Data Used in Testing?
January - December 2016

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 2016 data, there were 6,617 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?
There are 4,283,227 patient-months (449,110 patients) in total. Among all patient-months in 2016, the average age was 56.5 years old, 41.8% of patient-months were female, 55.2% were White, 37.3% were Black, 5.7% were Asian/Pacific Islander, 1.3% American Indian/Alaskan Native, 0.4% were other/Multi-racial/unknown/missing. And 20.0 % were Hispanic. At patient level, the mean of age was 56.5 years old. 41.9% of them were female. For race, 56.7% were White, 36.0% were Black, 5.6% were Asian/Pacific Islander, 1.3% were American Indian/Alaskan Native, and the rest 0.4% were other/Multi-racial/unknown/missing. There were 19.2% Hispanic patients. 80.4% were non-Hispanic, 0.4% were unknown or missing.

1.7 Sample Differences, if Applicable

N/A

1.8 What were the patient-level sociodemographic (SDS) variables that were available and analyzed in the data or sample used? For example, patient-reported data (e.g., income, education, language), proxy variables when SDS data are not collected from each patient (e.g. census tract), or patient community characteristics (e.g. percent vacant housing, crime rate).

Patient level:

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

*Assessed at a specific time point (e.g., at the first ESRD service date). Medicare coverage in model was defined as:
1. Medicare as primary and Medicaid
2. Medicare as primary and NO Medicaid
3. Medicare as secondary or Medicare HMO (e.g. Medicare Advantage)
4. Non-Medicare/missing

Data on patient level SDS/SES factors obtained from Medicare claims and administrative data.
ZIP code level – Area Deprivation Index (ADI) from 2014 Census data.

2a.2—Reliability Testing
2a2.1. Level of Reliability Testing
Performance measure score

2a2.2. Method of Reliability Testing
Inter-unit reliability (See appendix for detail)

2a2.3. Statistical Results from Reliability Testing
The IUR value is 0.80. Facilities with <11 eligible patients were excluded from this calculation.

2a2.4. Interpretation
This value of IUR indicates that about four-fifths of the variation in the PPPW can be attributed to the between-facility differences (signal) and about one-fifth to within-facility variation (noise). This value of IUR implies a high degree of reliability.

2b2—Validity Testing

2b2.1. Level of Validity Testing
Performance measure score (empirical validity testing, face validity)

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, 2013-2016) 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 in 2013-2016. There are 4,857 facilities available for comparison.

We further examined the relationship between PPPW and other related measures, i.e. 2013-2016 Standardized Mortality Ratio, 2016 Standardized Hospitalization Ratio (admissions), 2016 Standardized Hospitalization Ratio (ED visits), 2016 Standardized Readmission Ratio.

2b2.3. Statistical Results from Validity Testing
The Spearman correlation coefficient between facility waitlist rate and STR was significant: rho=0.45, p<.0001. There is also significant correlation between PPPW and the SMR (n=6,086, r=-0.11, p<.001), SHR (admissions) (n=6,400, r=-0.03, p<.001), SHR (ED visits) (n=6,400, r=-0.22, p<.001), and SRR (n=6,375, r=-0.03, p<.001).

2b2.4. Interpretation
Percentage of Prevalent Patients Waitlisted (PPPW) is positively correlated with STR, suggesting that facilities with higher waitlisting rates also have higher transplant rates. The Spearman correlation between PPPW and other measures indicates that higher waitlisted rate is associated with lower mortality rate, lower hospitalization rate and lower readmission rate.

2b3—Exclusion Analysis

2b3.1. Method of Testing Exclusion
In order to see the differences with and without excluding nursing home patients, the number of patient-months before and after exclusion were compared (Table 3). In Figure 1, we show a histogram of patient-months excluded by facility. Additionally, in Table 4 we compare the quantiles of crude percentage waitlisted (before versus after exclusion).

2b3.2. Statistical Results From Testing Exclusion
Table 3. Patient-months before and after excluding nursing home and hospice patients, 2016

	Before exclusion	After exclusion	Percentage excluded
Numbers of Patient-months	4,594,717	4,283,227	6.8%

Figure 1. Histogram of patient-months excluded, at facility level, 2016

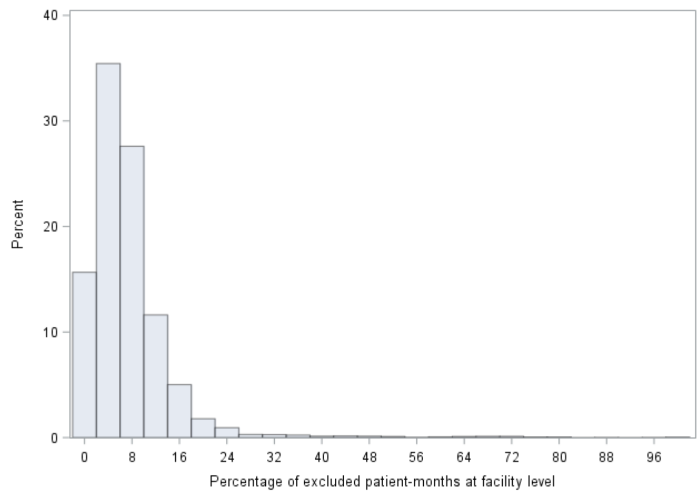


Table 4. Quantiles of crude waitlist rates before and after exclusion, 2016

	Mean (Std)	Q1 (25%)	Q2 (50%)	Q3 (75%)	Q4 (100%)
Before exclusion	0.19 (0.12)	0.11	0.18	0.26	1.00
After exclusion	0.20 (0.12)	0.12	0.19	0.27	1.00

2b3.3. Interpretation
Figure 1 reveals variation in the percent of excluded patients across facilities and Table 4 shows some change in the distribution of scores, 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

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.

A linear spline was used to model the effect of (continuous) age. The spline's knots were determined empirically using standard techniques. Specifically, as an initial step, we categorized age into as many groups as the data would sustain (15 groups). We then estimated the effect of categorical age, then plotted the age-category-specific parameter estimates against their respective category-specific median ages. The shape of this plot indicates age intervals within which the slope is approximately constant, and similarly suggests ages at which the slope changes. Using this procedure and examining the plot in Figure 3, knots at 15, 55 and 70 were suggested.

In response to the requirements for NQF's Trial Period for the incorporation of sociodemographic factors into quality measures, we investigated several patient and zip code level data elements (see list in 1.8). Sociodemographic factors included in the analysis were based on conceptual criteria and empirically demonstrated findings in the literature, which have shown that barriers to waitlisting exist among racial minorities, women and the poor. In addition, the particular patient and area level variables chosen were based on availability of data for the analyses. We were able to acquire individual area-level variables included in the Area Deprivation Index (ADI) developed by Singh and colleagues at the University of Wisconsin[1].

2b4.4. Statistical Results

Table 5. Coefficients and p-value in final PPPW model (note: $a_+=\max(a,0)$), 2016

Covariate	Coefficient	p-value
Age	0.06	<.001
$(age-15)_+$	-0.08	<.001
$(age-55)_+$	-0.03	<.001
$(age-70)_+$	-0.23	<.001

2b4.4b. Describe the analyses and interpretation resulting in the decision to select SDS factors (e.g. prevalence of the factor across measured entities, empirical association with the outcome, contribution of unique variation in the outcome, assessment of between-unit effects and within-unit effects)

The table below shows the parameter estimates for model including all SDS/SES variables along with original covariates.

[1] Singh, GK. Area deprivation and widening inequalities in US mortality, 1969–1998. Am J Public Health. 2003;93(7):1137–1143.

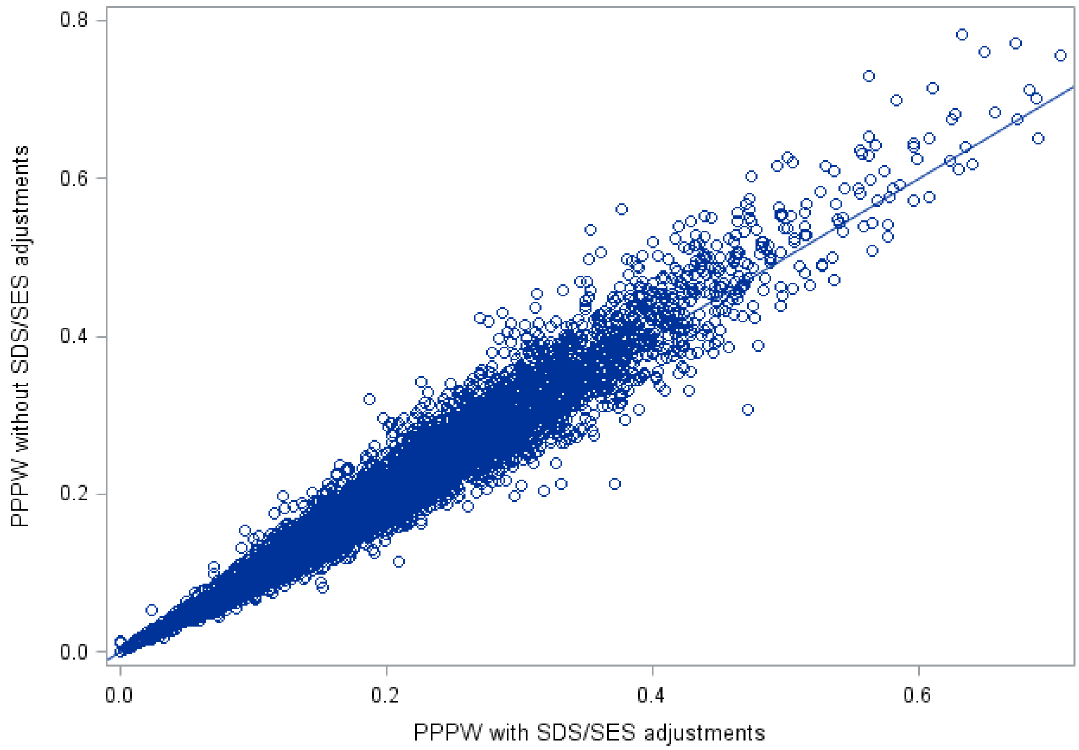
Table 6. Estimate and p-value of SES/SES variables, 2016

Covariate	**Estimate**	**P**
Sex		
Male	Reference	
Female	-0.08	<.01
Race		
White	Reference	
Non-White	0.03	<.01
Ethnicity		
Hispanic	0.11	<.01
Non-Hispanic	Reference	
Employment status		
Employed	0.66	<.01
Unemployed	-0.01	0.35
Retired/ Missing	Reference	
Medicare coverage		
Medicare as primary with Medicaid	Reference	
Medicare as primary without Medicaid	0.37	<.01
Medicare as secondary	0.29	<.01
Non-Medicare/missing	-0.63	<.01
ADI index	-1.03	<.01

Patient-level SDS/SES: Compared to male, female patients were less likely to be waitlisted (OR=0.92, p<.01). Hispanic patients were more likely to get waitlisted compared with non-Hispanic (OR=1.12, p<.01). Compared to retired/missing employment status patients, employed patients were more likely to get waitlisted (OR=1.93, p<.01); contrarily, unemployed patients were less likely to be waitlisted though the effect was not significant (OR=0.99, p=0.35). For insurance coverage, compared with Medicare as primary with Medicaid, patients with Medicare as primary without Medicaid and Medicare as secondary were more likely to be waitlisted (OR=1.45, p<.01; OR=1.34, p<.01), the non-Medicare/ missing group were less likely to get waitlisted (OR=0.53, p<.01).

Area-level SDS/SES: Patients in higher area-level deprivation (ADI), i.e. more deprived area, were less likely to be waitlisted (OR=0.36, p<.01).

Figure 2. Correlation between PPPWs with and without SDS/SES adjustments



The standard and SDS/SES-adjusted PPPW were highly correlated at 0.98 (*p*<.001).

Table 7. Flagging rates between original PPPW and PPPW adjusted for SES/SDS, 2016*

	PPPW with SDS/SES adjustment			
Standard PPPW	**Better than expected**	**As expected**	**Worse than expected**	**Total**
Better than expected	793	181	0	974 (14.75%)
As expected	91	5350	22	5463 (82.72%)
Worse than expected	0	44	123	167 (2.53%)
Total	884 (13.39%)	5575 (84.42%)	145 (2.20%)	6604

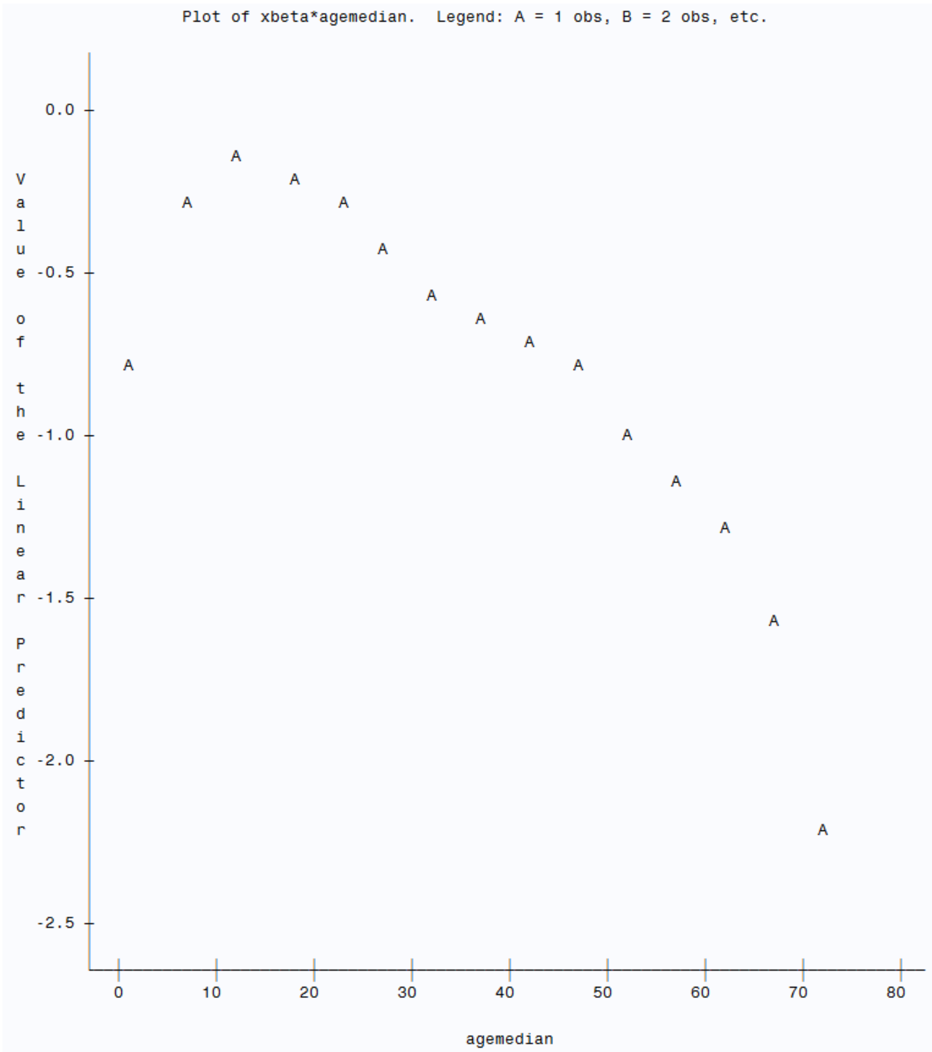
* Facilities with less than 11 patients were excluded.

After adjustment for SDS/SES, 338 facilities (5.1%) changed performance categories; 203 (3.1 %) performed worse after SDS/SES adjustment.

Patient level-variables such as employment, ethnicity, and health insurance had significant effects on waitlisting, as well as area-level variables. Although SDS/SES does affect waitlisting rates these were not included in the measure specification on biological/clinical grounds. Namely, there is no biological or clinical rationale to exclude patient groups on the basis of race, sex or economic status from transplantation as these groups still stand to substantially benefit from transplantation. Although barriers exist to waitlisting in these groups, it is expected that facilities should work towards helping such patients overcome those issues.

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

Figure 3. Plot of age trend (linear predictor versus median of age)



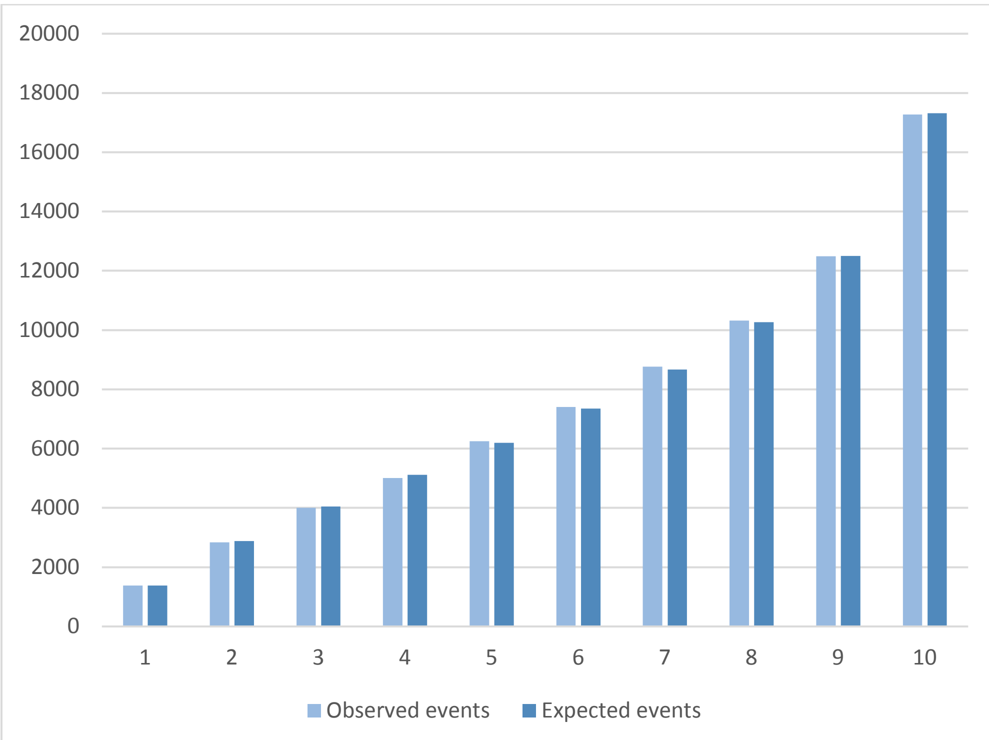
2b4.6. Statistical Risk Model Discrimination Statistics (e.g., c-statistic, R^2)

The C-statistic (also known as the Index of Concordance) was 0.72. This indicates that the model correctly ordered 72% of the pairs of patient-months that were discordant with respect to the response variate. Month-specific C statistics were computed, in order to identify any trends by month in the model's discriminatory ability, and for computational ease.

2b4.7. Statistical Risk Model Calibration Statistics (e.g., Hosmer-Lemeshow statistic)
The Hosmer-Lemeshow (H-L) statistic is defined strictly for independent trials, and months within-patient are expected to be highly correlated. We therefore chose to compute the H-L statistic in a month-specific fashion. No evidence of model mis-fit was detected for any month, with the p values being generally quite high (e.g., p=0.53 for January).

2b4.8. Statistical Risk Model Calibration—Risk decile plots or calibration curves
In Figure 3, we plot the key components of the Hosmer-Lemeshow test; namely, the observed and expected number of patients waitlisted by risk decile.

Figure 4. Observed and expected waitlist counts by risk decile



2b4.9. Results of Risk stratification Analysis
N/A

2b4.10. Interpretation

The plot in Figure 4 reveals that in no decile is there a practically important discrepancy between the observed number of waitlisted patients in a decile and that predicted by the model.

2b4.11. Optional Additional Testing for Risk Adjustment
N/A

2b5—Identification of statistically significant and clinically meaningful differences
2b5.1. Method for determining
See appendix

2b5.2. Statistical Results

Table 8. Number and percentage of facilities by classification of the Waitlist Rate.*

Classification	N (%)	Median of PPPW
Better than expected	974 (14.7%)	0.37
As expected	5476 (82.8%)	0.17
Worse than expected	167 (2.5%)	0.04
Total	6617 (100%)	0.19

* Facilities with less than 11 patients were excluded.

2b5.3. Interpretation
As is evident in Table 8, most facilities (82.8%) had a PPPW that was "As expected". Approximately 14.7% of facilities had a PPPW that was "Better than expected", while nearly 2.5% were "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
2b6.2. Statistical Results
2b6.3. Interpretation

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

Planned use in public report, payment programs

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

N/A

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

CMS will decide if and when the measure should be implemented into a public reporting program.

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

CMS will decide if and when the measure should be implemented into a public reporting program.

4b.1. Progress on improvement

N/A

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

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

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

5a—Harmonization

5a.1. Are the measure specifications completely harmonized

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

5b—Competing measures

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

PPPW Appendix C Text

2a2.2. Method of Reliability Testing

We used January 2016 – December 2016 data to calculate facility-level annual performance scores. The NQF-recommended approach for determining measure reliability is a one-way analysis of variance (ANOVA), in which the between-facility variation (σ_b^2) and the within-facility variation ($\sigma_{t,w}^2$) in the measure is determined. The inter-unit reliability (IUR) measures the proportion of the total variation of a measure (i.e., $\sigma_b^2 + \sigma_{t,w}^2$) that is attributable to the between-facility variation, the true signal reflecting the differences across facilities. We assessed reliability by calculating inter-unit reliability (IUR) for the annual performance scores. A small IUR (near 0) reveals that most of the variation of the measure 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 Percentage of Prevalent Patients Waitlisted (PPPW) for N facilities. Since the variation in $T_1,\ldots,T_N$ is mainly driven by the estimates of facility-specific intercepts ($\alpha_1,\ldots,\alpha_N$), we use their asymptotic distributions to estimate the within-facility variation in PPPW. 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-facility variance in PPPW can be estimated by

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

and the total variation in PPPW 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 facility, $\bar{T} = \Sigma\, n_i T_i / \Sigma\, n_i$, and

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

is approximately the average facility size (number of patients per facility). 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 PPPW calculation only included facilities with at least 11 patients during the entire year.

2b5.1. Method for determining identification of statistically significant and clinically meaningful differences

Since the distribution of waitlist rates are slightly skewed, logit transformation was used to reduce the skewness. Denote as the estimated waitlist rate for each facility, *j*=1,2, …,N. Set $\hat{g}_j = \log\frac{\hat{\varphi}_j}{1-\hat{\varphi}_j}$. So the formula for Z scores would be

$$\hat{Z}_j^g = \frac{\hat{g}_j - \overline{g(\hat{\varphi}_j)}}{SE\{\hat{g}_j\}}$$

where $g(\hat{\varphi}_j)$ is the average of the $\hat{g}_j$ national PPPW, and

$$SE\{\hat{g}_i\} = \frac{1}{\hat{\varphi}_j(1-\hat{\varphi}_j)} SE\{\hat{\varphi}_j\},$$

is the standard error after transformation and $SE\{\hat{\varphi}_j\}$, is obtained through the Delta method.

Then two-sided test with significant level 0.05 was used. Note that the reference distribution was Efron's empirical null, which essentially re-scales the critical value for the test statistic. The rescaling multiple is estimated by the slope (estimated via robust regression) correlating the empirical and theoretical Z score quantiles (e.g., with a multiple of 1 indicating that in fact no rescaling is required). Facilities are flagged if they have outcomes that are extreme when compared to the variation in national waitlist rate.