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Development and Validation of a Socioeconomic Kidney Transplant Derailers Index (KTDI)

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List of Abbreviations

ADI: Area Deprivation Index

DDKT: deceased donor kidney transplant

HR: hazard ratio

KT: kidney transplant

KTDI: Kidney Transplant Derailers Index

LDKT: living donor kidney transplant

SES: socioeconomic status

Abstract

Background. Socioeconomic derailers are barriers to kidney transplant (KT) but are difficult to measure quickly in clinical settings. We created and validated a single score Kidney Transplant Derailers Index (KTDI) for individual KT patients.

Methods. The primary dataset included 733 patients presenting for KT evaluation in California. A secondary sample of low income (250% of poverty level or lower) dialysis patients were considered for comparison. Exploratory factor analysis was used to determine which derailers represented patients' socioeconomic status and weight KTDI scores (T-score, mean = 50 and SD = 10). Potential KT derailers included health insurance, employment, financial insecurity, educational attainment, perception of neighborhood safety, access to a vehicle, having a washer/dryer, and social support level. Construct validity was tested with associations between the KTDI and the Area Deprivation Index (ADI). For patients presenting for KT, we tested associations between the KTDI and time to KT waitlisting and living donor KT (LDKT).

Results. Nine dimensions were retained as the best indicators of KT derailers, omitting only social support level from the original set of derailers considered. KTDI scores ranged from 37.1 to 74.3 (Mean: 50, SD: 10; higher scores indicate greater derailers). In the sample of low income dialysis patients, the mean KTDI score was over a standard deviation higher at 62.8. The KTDI was associated with the ADI ($\gamma = 0.11$, SE = 0.01, $p<0.001$). In comparison to those with > median KTDI, patients with $\leq$ median KTDI had

higher probability of waitlisting (66% vs. 33%, p<0. 001) and receiving a LDKT (26% vs. 5%, p<0.001).

Conclusions**.** The KTDI is a valid and efficient indicator of socioeconomic barriers to KT for individual patients that can facilitate comparisons between patients and help target patients for interventions to improve KT access.

Introduction

Though kidney transplantation is the medically optimal treatment for end stage kidney disease (ESKD), completing transplant evaluation and receiving a transplant is complex. Also, prior to ESKD, many kidney patients, particularly Black and Hispanic patients (1), face greater levels of socioeconomic challenges including greater levels of neighborhood violence (2, 3), employment instability, and not having access to a car (4, 5) or basic amenities like a washer or dryer (6). After a diagnosis of ESKD, even more socioeconomic challenges emerge including patients becoming unemployed at greater rates (7, 8), starting disability (8), and, if transplanted, requiring health insurance coverage to pay for lifetime immunosuppressant medications (9). For these reasons, lower socioeconomic status (SES) in kidney patients is associated with lower likelihood of receiving a DDKT or LDKT (10, 11).

However, measurement of individual and community level indicators of SES in transplant research and clinical settings is inconsistent. Published literature uses many different individual measures of SES, including patients' educational level (1, 12, 13), income (11), type of health insurance (1, 11-14), and employment status (1), but often fails to assess multiple aspects of SES at the same time. Neighborhood or zip code community level indexes from Census data, with indicators like the percentage of individuals in

poverty, percentage of individuals with college education, value of owner-occupied homes, and the level of racial segregation (9, 10) have also demonstrated associations with reduced access to transplant (10), as well as with transplant outcomes (12). Finally, while multiple, well-validated community-level SES indices are available (15, 16), fewer multidimensional individual-level indexes at the patient level exist.

A kidney transplant-specific, individual level index capturing multiple SES barriers to transplant in one score could ease the burden of clinical screening and risk-stratify patients with higher rates of SES challenges requiring additional support. This manuscript details the creation and validation of a single score Kidney Transplant Derailers Index (KTDI) using diverse samples of patients recruited from dialysis centers and from a transplant center while presenting for transplant evaluation. Validation analyses for the new KTDI included examining associations with a community level SES index and with kidney transplant waitlisting and LDKT receipt.

Materials and Methods

Study Samples

The primary dataset used for this study was collected in a randomized controlled trial testing the impact of kidney transplant education and tailored behavior change feedback on transplant knowledge, informed decision-making, attitudes, and access to transplant; its protocol has been published elsewhere (17). This study recruited 733 Hispanic, non-Hispanic Black, non-

Hispanic White, and non-Hispanic patients of other races when they presented for transplant evaluation at an academic kidney transplant center in Southern California. This study's baseline data (prior to the educational intervention) was used for scale development and the majority of validation analyses. In addition, data from a second randomized controlled trial with 561 Black and White dialysis patients with low income (defined as annual household income of 250% of the federal poverty level) from 122 dialysis clinics throughout the state of Missouri was used for select validation analyses (18). These samples were given identical survey measures (described below), including identical questions regarding potential transplant derailers. The UCLA Institutional Review Board approved the protocols used to collect the data in both studies (transplant patient study: #14-000802; dialysis patient study: #14-000382), and in both, the participants were treated in a manner in accordance with the Declaration of Helsinki and the Declaration of Istanbul.

Measures

Patient-Level Measures. Patients were surveyed about the presence or absence of 10 SES indicators assessed on pre-intervention surveys in their respective studies. These included: 1) having no full time employment; 2) use of disability employment; 3) having no private health insurance; 4) use of Medicaid; 5) financial insecurity, defined as being able to live < 2 months without current income; 6) having low educational attainment, defined as having a high school degree or less education; 7) feeling unsafe in the

patient's neighborhood; 8) having no access to a vehicle; 9) having no washer and dryer at home; and 10) having less social support than the patient requires. Each of these indicators, or kidney transplant derailers, were coded as presence vs. absence of the specific derailer (1 vs. 0). This coding sets the direction of the index we aimed to create, which focuses on the derailers (e.g. higher vs. lower derailers) instead of SES (e.g., higher vs. lower SES).

In addition to the derailer variables, we collected data on patients' demographic and clinical characteristics. These included patients' age, race/ethnicity (Hispanic, non-Hispanic Black, non-Hispanic White, non-Hispanic other race), gender (male, female), and patient reported health status (rated as excellent to poor). In addition, we assessed patients' level of health literacy by determining whether the patient ever needed help reading hospital materials (yes vs. no).

Finally, we used the transplant center medical records to determine the time to transplant waitlisting and time to LDKT for each patient (transplant sample only). The data for these analyses were downloaded on 11/03/2017, making this the default administrative censor date. Otherwise, for the time to waitlisting analysis, patients were censored when they died or were marked in the chart as permanently ineligible for transplant. For the time to LDKT analysis, patients were censored when they died, received a DDKT, or were marked in the chart as permanently ineligible for transplant.

For each outcome, we calculated the number of days from the survey to the event (waitlisting or LDKT) or censor date.

Zip Code SES Index. Finally, we also supplemented our individual level SES indicators with a new, well-validated zip code-level SES index called the Area Deprivation Index (ADI).(15, 19) The ADI draws data from the US Census on 17 SES indicators (e.g., percent of families below the poverty level, percent of households without a motor vehicle), then weights for these indicators were used to generate a score ranging from 0-100, with higher scores indicating greater deprivation.

Statistical Analyses

Statistical analyses were conducted in SAS v9.4 or R v3.4.3 (20, 21). For all statistical tests, a p-value < 0.05 was considered statistically significant. To describe and summarize patient characteristics, we calculated frequencies and percentages for categorical variables, and means, standard deviations and ranges for continuous variables.

Creation of the Derailers Index. We conducted several analyses to create the kidney transplant derailers index, all using the transplant patient sample (n=733). First, since each derailer indicator was coded to be dichotomous, tetrachoric correlations between each pair were estimated. Cohen's conventions for magnitude of correlations were used to determine the size of correlations: small = $0.10 \leq r < 0.243$; medium = $0.243 \leq r < 0.371$; large = $r \geq 0.371$ (22) . These cutoffs correspond to small, medium,

and large magnitude of standardized effect sizes. Next, an exploratory factor analysis was performed using principal factoring on the derailer indicators' tetrachoric correlation matrix. First, we examined the results of this factor analysis to determine whether the indicators formed a unidimensional scale; i.e., whether or not indicators measured a single, underlying construct. The ratio of the first to second eigenvalue >3 from the factor analysis was used as the cutoff to indicate unidimensionality (23). If unidimensionality was established, we then examined the factor loading for each indicator, and retained indicators with factor loadings of $\geq$0.40 for inclusion in the index. Finally, after selecting indicators for inclusion in the index, we calculated a score by first multiplying each indicator by its standardized scoring coefficient from the factor analysis, then transformed this to a T-score (mean = 50; SD = 10). Higher T-scores on the index indicate greater presence of kidney transplant derailers.

Validation Analyses. After creating the index, several types of validity were examined. First, we examined the distribution of index scores in this sample. Since the dialysis sample had as an inclusion criterion that patients were low income (annual household income of 250% of the federal poverty level), we hypothesized that kidney transplant derailers index scores would be higher than in the transplant sample.

Next, "known groups" validity (a test of construct validity) was tested by determining whether the kidney transplant derailers index distinguished between pre-specified categories of race/ethnicity, health status, and health

literacy. The hypotheses for these tests were: (1) non-Hispanic Black patients would have higher transplant derailers scores vs. other racial/ethnic groups; (2) patients with "Fair/Poor" self-rated health would have higher transplant derailers index scores in comparison to patients with "Excellent/Very Good/Good" self-rated health; and 3) patients with lower health literacy would have higher transplant derailers scores than patients with higher health literacy. We used 1-way ANOVA or independent samples t-tests, as appropriate, to test these hypotheses, and significant differences in mean transplant derailers index scores in the hypothesized direction were taken as evidence of construct validity. In addition, for each of these tests, Cohen's *d* was computed as a measure of standardized effect size. Cohen's conventions for magnitude of effect sizes was used: small = $0.20 \leq d < 0.49$; medium = $0.50 \leq d < 0.79$; large = $d \geq 0.80$ (22).

Next, criterion validity was assessed by testing the association between the kidney transplant derailers index and the ADI. Since both the kidney transplant derailers index and the ADI measure nearly the same construct, we hypothesized a statistically significant, positive association. As the ADI is a zipcode-level measure, with individual patients nested within zipcodes, we used a mixed effects model accounting for this clustered relationship.

Finally, we examined predictive validity by testing the association between time to waitlisting and LDKT stratified by the kidney transplant derailers index score above the median vs. median and below with separate

Kaplan-Meier failure plots and log-rank tests. We hypothesized that patients with above median derailers index scores would have significantly lower probability of waitlisting and LDKT receipt in comparison to patients with median or below scores.

Results

Patients and Frequency of Kidney Transplant Derailers

Among the 733 patients included in the transplant sample, the mean age was 53 years, and the largest proportion were Hispanic (38%). A minority were female (39%), and patient-reported health status was split evenly between “Excellent/very good/good” (52%) and “Fair/poor” (48%). (Table 1.) In the dialysis sample (n=561), patient characteristics were largely similar, except that a larger proportion of patients were non-Hispanic Black (71%) and female (49%). (Table 1.) The most common kidney transplant derailer experienced was having no full time employment (77%), followed by having no private insurance (46%), and use of disability employment (36%). (Figure 1.) The least common derailers were not having a washer or dryer (17%), having less than needed social support (11%), and not having access to a vehicle (10%).

Creation of Kidney Transplant Derailers Index

We conducted multiple psychometric analyses to create the Kidney Transplant Derailers Index. Tetrachoric correlations between several kidney transplant derailers exceeded the cut-off for large magnitude.

(Supplementary Figure 1.) Correlations of the largest magnitude were between having no fulltime employment, use of disability employment, having no private insurance, use of Medicaid insurance, and financial insecurity. Having no access to a vehicle evidenced a large correlation with several of these variables as well. Having less than needed social support tended to have small correlations with other derailers.

The exploratory factor analysis indicated that these derailers were unidimensional with a first to second eigenvalue ratio of 3.92/0.98= 4.00. The factor loadings for all derailers exceeded 0.40 except not having adequate social support (loading = 0.29). (Table 2) Therefore, we omitted this variable and re-ran the exploratory factor analysis to obtain standardized scoring coefficients. In the second run, unidimensionality was again evidenced, all factor loadings exceeded 0.40, and the 9 derailers accounted for 75% of the variance of the underlying factor suggested by the factor model.

We then created a kidney transplant derailers index (KTDI) from the following derailers: having no full time employment; use of disability employment; have no private health insurance; use of Medicaid; financial insecurity; low educational attainment; having no access to a vehicle; feeling unsafe in the neighborhood; and not having a washer and dryer at home. After weighting by the standardized scoring coefficients from the factor model and transforming to the T-score metric, the mean KTDI score was 50,

median was 47.3, and ranged between 37.1 and 74.3. (Table 3.) Scoring instructions are provided in Supplementary Materials.

Validation Analyses for the Kidney Transplant Derailers Index

The mean KTDI score in dialysis sample was over a standard deviation higher than in the transplant sample (62.8 vs. 50.0, Table 3.). Next, since social support was not selected for inclusion in the KTDI, it was determined ad hoc to use it as a criterion variable in validity analyses. In construct validity tests, associations of the KTDI with race, health status, social support, and health literacy were statistically significant in the hypothesized directions. The magnitude of effect sizes ranged widely (Table 4). The strongest associations were with the KTDI and race/ethnicity, with Black patients having the highest level of kidney transplant derailers.

In addition, there was a significant, positive association between the KTDI and ADI score for the patient's zip code ($\gamma = 0.114$, SE = 0.02, $p<0.001$). In other words, a 10 point increase in the ADI score for the patient's zip code is associated with a 1.14-point increase in the KTDI. These findings support the validity of the KTDI, since a positive association between individual and neighborhood level SES is expected.

In comparison to those with an above median index score, patients with a median or below KTDI score had a significantly higher probability of waitlisting for transplant, at 66% vs. 33%, respectively (log rank p<0. 001). Similarly, patients with a median or below KTDI score had a significantly

higher probability of LDKT, at 26% vs. 5%, respectively (log rank $p<0.001$). (Figures 2a and 2b.)

Discussion

In this paper, we have shown that the KTDI is a valid and efficient indicator of socioeconomic barriers to kidney transplantation that predicts waitlisting and LDKT outcomes. The KTDI can facilitate comparisons between patients of different SES levels in research. In addition, it can assist in targeting patients in need of interventions to overcome socioeconomic challenges to successful transplant. Unlike other SES indexes used in transplant research, the KTDI tracks individual barriers instead of community level barriers, which may make the KTDI more appropriate for clinical screening.

The KTDI represents, to our knowledge, the only kidney transplant-targeted barriers index. Moreover, the KTDI represents a rare individual-level scale measuring socioeconomic barriers. While community-level socioeconomic indexes like percentage of persons in poverty within a zip code or neighborhood (14) and indexes including population density, average property value, average household income, and percent of individuals who are unemployed (10, 24) are readily available and do not require patient surveying, they cannot pinpoint the specific socioeconomic characteristics of individual patients, and there may be socioeconomic heterogeneity within a given neighborhood or zipcode. For this reason,

interventions to overcome challenges for individuals at higher risk for dropping out and not receiving an LDKT cannot be easily inferred from community level SES measures (9).

Our approach to creation of the KTDI responds to a recent call for greater application of psychometric approaches to developing SES indexes (25). After using psychometric approaches (e.g., factor analysis) to identify the most salient transplant derailers, the KTDI demonstrated evidence of validity, supporting its suitability for use in clinical screening. Most importantly, the KTDI was a strong predictor of time to waitlisting and LDKT receipt; patients with median or lower KTDI scores tended to access transplant much more quickly.

The KTDI may be useful to transplant programs aiming to identify transplant candidates at greatest risk for not receiving transplants. In this study sample, Black patients had the highest level of kidney transplant derailers compared with other groups. Such patients could be targeted for interventions to help overcome socioeconomic barriers to transplant. For example, the Your Path to Transplant program identified patients presenting for transplant evaluation with socioeconomic barriers, then supplied these patients with a resource manual with references for resources like transportation assistance (17). In that study, the KTDI could have been used to identify patients in most need of socioeconomic resources. Additionally, even though the KTDI captures multiple socioeconomic barriers in a single

score, its individual items can be used to specify the particular barrier or barriers a patient is experiencing, and focus on those for intervention.

The KTDI may also be useful in other types of research. One use may be as a tool to help stratify patients into different cohorts based on level of SES. Additionally, the KTDI may serve as a kidney transplant-specific SES covariate in studies of transplant access. The results of this study indicate that individual-level SES barriers to kidney transplant, as measured by the KTDI, had statistically significant association with transplant waitlisting and LDKT receipt. Patzer and McClellan put forth a multilevel framework for heath disparities for chronic kidney disease (9). This framework separates SES factors that impact chronic kidney disease risk and outcomes into community and individual levels. In another conceptual analysis of health disparities in kidney transplant, Waterman and colleagues identified barriers to transplant across multiple levels, including the patient and family, social network, healthcare provider, health care system, and the community and society levels (26). Both of these conceptual models draw directly or indirectly from the socioecological model (27), under which analyses of health risks, behaviors, and outcomes should incorporate factors across multiple levels simultaneously, including the individual and the community (28). In this context, the KTDI may be viewed as an individual-level complement to community level measures of SES that are more often used in transplant research.

Like all studies, this study has important limitations to consider when interpreting its results. First, though the patient samples used for this study are diverse, both geographically and in terms of demographic characteristics, they are likely unrepresentative of larger populations of kidney transplant patients. Future validation studies of the KTDI should be conducted in national samples of patients. Next, while the KTDI covered many individual barriers to kidney transplant, other individual barriers not included in the KTDI may be important to kidney patients. Future work should examine whether inclusion of additional derailers improves the KTDI. Finally, though not strictly a limitation of the study itself, the individual barriers included in the KTDI are not available in established transplant registries. However, at only 9 indicators, the KTDI is brief, and several of the indicators are likely already collected by many transplant programs. By adding the remaining indicators to their intake packets, the KTDI could easily be calculated by transplant programs.

In conclusion, this valid KTDI index can be used in clinical and research applications for efficient assessment of an individual patient’s level of SES-related barriers to transplant and risk for dropping out of transplant evaluation or not receiving an LDKT. The ability to accurately assess and intervene with patients at highest risk can be improved by use of this index.

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Supplementary Materials

The Kidney Transplant Derailers Index (KTDI) is scored using the following formula. Each indicator is coded so that 1 = presence of the derailer and 0 = absence of the derailer. (Specific definitions of each indicator are given in the Methods.)

First, each indicator is multiplied by its appropriate weight.

$$KTDI_{raw} = no\,full time\,employment\,x\,0.18 + disability\,employment\,x\,0.19 + no\,private\,insurance\,x$$

Then, raw KTDI scores are converted to T-scores with a mean of 50 and standard deviation of 10. To do so, first, a standard z score is calculated:

$$KTDI_z = \frac{\left(KTDI_{raw} - \mu\right)}{\sigma}$$

Where μ is the sample mean of $KTDI_{raw}$ and σ is the sample standard deviation of $KTDI_{raw}$. Then, the T-score is calculated:

$$KTDI_T = \left(KTDI_z\,x\,10\right) + 50\;ADDIN$$

1

2

3

4

5

6

7

8