Published in final edited form as:

Curr Transplant Rep. 2018 March ; 5(1): 45–54.

The Living Donor Lost Wages Trial: Study Rationale and Protocol

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Abstract

Purpose of review—This paper describes the background, rationale, and design of an NIH-funded, single-center study to test the impact of offering reimbursement for donor lost wages incurred during the post-nephrectomy recovery period on the live donor kidney transplant (LDKT) rate in newly evaluated kidney transplant candidates, to examine whether offering reimbursement for donor lost wages reduces racial disparity in LDKT rates, and to determine whether higher reimbursement amounts lead to higher LDKT rates.

Recent findings—LDKT is the optimal treatment for renal failure. However, living kidney donation has declined in the past decade, particularly among men, younger adults, blacks, and low-income adults. There is evidence that donation-related costs may deter both transplant candidates and potential donors from considering LDKT. Lost wages is a major source of financial loss for some living donors and, unlike travel and lodging expenses, is not reimbursed by financial assistance programs.

Summary—The study addresses the transplant community's call to reduce the financial burden of living donation and examine its impact on LDKT rates. Findings have the potential to influence

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Compliance with Ethical Guidelines

Conflict of Interest

James Rodrigue, Aaron Fleishman, Michaela Carroll, Amy Evenson, Didier Mandelbrot, Prabhakar Baliga, David Howard, and Jesse Schold declare no conflict of interest. Martha Pavlakis reports consulting fees as a part of an end point adjudication committee for Shire pharmaceuticals and as the PI for a Novartis Study (TRANSFORM), a 24 month multi-center randomized safety and efficacy study in de novo renal transplant recipients.

Human and Animal Rights and Informed Consent

This article does not contain any studies with human or animal subjects performed by any of the authors.

Trial Registration: www.ClinicalTrials.gov, NCT03268850

policy, clinical practice, LDKT access, and income-related and racial disparities in LDKT and living donation.

Keywords

Living donation; kidney donation; financial neutrality; live donor kidney transplantation

INTRODUCTION

Patients who receive a living donor kidney transplant (LKD) live longer and have a better quality of life than patients who receive a deceased donor transplant or remain on dialysis.¹ In the last decade, 34–40% of transplanted kidneys in the United States were from living kidney donors. However, the number of living kidney donors has declined by approximately 15% since its peak in 2004.² This decline has been most prominent among men, younger adults, blacks, and low-income adults.^{3,4} Factors that may explain the decline include an aging kidney transplant candidate population (social networks contract as people age, thus yielding potentially fewer potential donors), increasing rates of diabetes and obesity in the general population, new transplant practice regulations, changes in donor selection criteria, and the financial impact of donation on living donors and their families.³

While living donors are not responsible for medical costs of donation evaluation and surgery, most incur direct costs for travel, lodging, meals, parking, childcare, medications, and other expenses associated with being evaluated for and recovering from donation.^{5–7} Indirect costs may include lost wages and the use of earned medical leave or vacation time. We previously reported that 92% of living kidney donors participating in the multi-center prospective Kidney Donor Outcomes Cohort (KDOC) study incurred direct costs (median \$433, range \$6 to \$10,240) and more than one-third (36%) of donors reported lost wages in the first year following donation (median \$2,712, range \$546 to \$19,728).⁸ These findings mirror those reported in Canada, where 96% of living kidney donors incurred donation-related costs and 47% lost wages. One-third incurred costs greater than \$3,000 (Canadian dollars) and 15% had costs exceeding \$8,000 (Canadian dollars).⁹

Donation-related costs may deter kidney transplant candidates from considering LDKT, and their friends and family from considering donation. In one study, nearly half of the kidney transplant candidates, deceased donor recipients, and LDKT recipients surveyed reported not talking to potential living donors due to concerns about the impact of lost wages on the donor.¹⁰ One-third (36%) reported being told by a family member or friend that they were willing to consider donation but were concerned about lost wages. Of these, 61% did not undergo donation evaluation. Minority and lower-income patients were more likely to report that they did not discuss or pursue LDKT because of concerns for financial burden to the donor. Other studies have also found that concerns about costs and lost wages discourage potential living donors.^{11,12}

The national decline in living kidney donation occurred during the recession. Some have postulated that unemployment, stagnant wages, and heightened economic insecurity, particularly among low wage earners, may have accelerated the decline in living donation.^{3,6,13} Gill et al.^{4,14} found that living kidney donation increased the most among higher

income groups from 1999 to 2004. However, since 2004, living donation has declined the most in low income groups, thus amplifying the income disparity in donation rates. The living donation decline has been most dramatic in low-income blacks relative to all other racial/ethnic and income groups combined.⁴ It is possible that financial disincentives are exacerbating racial disparities in LDKT rates. In 2016, for instance, LDKT accounted for 42% of all kidney transplants among whites, but only 13% of transplants among blacks, 23% among Asians, and 26% among Hispanics.²

In 2006, Congress authorized the Department of Health and Human Services to establish the National Living Donor Assistance Center (NLDAC, www.livingdonorassistance.org), which provides eligible living donors with up to \$6,000 in reimbursement for travel and lodging expenses associated with donation.¹⁵ Many recipients report that they would not have been able to donate without assistance from NLDAC.^{15,16} NLDAC is means-tested, notably based on both the living donor and transplant candidate household income, and is designed to be a “last resort” financial assistance program.¹⁷ Under these constraints, the program has provided financial assistance to only 5–10% of living donors since program inception.^{15,17} Living donors could seek reimbursement from their transplant recipient, but this is very uncommon. The median household income of kidney transplant recipients is nearly identical to that of their living donors.¹³ In our multisite KDOC study, only 6% of living kidney donors received any type of expense reimbursement from the recipient, which is not surprising given that many recipients are medically disabled, unable to work, and burdened by their own healthcare costs and living expenses.⁸ Importantly, although the National Organ Transplant Act permits reimbursement of donor lost wages in addition to direct travel and lodging costs,¹⁸ NLDAC does not cover lost wages.

There is general agreement in the transplant community that living donors should not suffer financial hardship for a surgery and related care that is medically unnecessary for their own health yet provides substantial benefit to the patient and to society.^{6,7,19–26} Financial neutrality, i.e., reimbursing or covering all direct and indirect costs related to living donation, has been advanced as a laudable goal designed to reduce or eliminate financial disincentives to donation.^{23,25} Several states allow living donors to deduct non-reimbursed donation expenses, including lost wages. However, state tax benefits have no effect on rates of living donation or LDKTs.^{27–29} Only 36% of U.S. tax payers itemize deductions, including only 18% of those earning \$50,000 and only 20% of racial minorities.³⁰ Also, the maximum tax benefit is small (\$600 on average) because only a small proportion of the actual costs can be claimed, which is not enough to offset lost wages incurred by most living donors.²⁹

Reimbursement of lost wages for living donors has been recommended as a critical step in helping to make living donation financially neutral.^{9,19,23,24} Over three-quarters of American Society of Transplant Surgeons (ASTS) members support reimbursement for lost wages. Support is high among the general public, health professionals, and adults with kidney failure.^{32–38} Several countries (e.g., Canada, Australia, Holland, Israel) have reimbursement programs that cover lost wages, either in whole or in part. However, the impact of these programs on LDKT rates has not been examined. Moreover, each country uses a slightly different maximum reimbursement amount – the differential impact of different wage reimbursement amounts is unknown. Recently, the Laura and John Arnold

Foundation funded the American Society of Transplant Surgeons to conduct a randomized, controlled study of lost wage reimbursement on living donation rates. However, details regarding this trial and its design have not yet been made public (<https://asts.org/news-and-publications/asts-news/article/2016/12/21/lost-wages-reimbursement-for-living-organ-donors-trial-announced#.WejUNo9Sx8w>).

Study Overview and Aims

We designed a single-center study using a blended randomized trial and historically controlled design in which 350 kidney transplant candidates are randomly assigned 1:1 to one of two parallel arms: (1) possible reimbursement of living donor lost wages up to \$1,500 (LW-1500) or (2) possible reimbursement of living donor lost wages up to \$3,000 (LW-3000). We will compare LDKT rates among study patients 12 months following initial transplant evaluation to rates among 350 historical controls matched for age, race/ethnicity, and household income. We will also examine whether the proportional difference in LDKT rate (12 months following initial transplant evaluation) between white and minority patients differs between study patients and matched historical controls.

The study has three aims: (1) test the effectiveness of offering reimbursement for living kidney donor lost wages on the LDKT rate in kidney transplant candidates; (2) examine whether offering reimbursement for living kidney donor lost wages reduces racial disparities in LDKT rates; and (3) determine whether higher reimbursement amounts lead to higher LDKT rates. We hypothesize that offering reimbursement for living donor lost wages will yield higher LDKT rates relative to historical controls, and will reduce the disparity in LDKT rates between white and minority patients. We hypothesize that kidney transplant patients assigned to the LW-3000 arm will have a higher likelihood of LDKT, 1 living donor inquiry, and 1 living donor evaluation by the 12-month study endpoint, compared to those patients in the LW-1500 arm.

Study Participants

Kidney Transplant Candidates—A primary sample of 350 kidney transplant candidates who present to the transplant center for initial multidisciplinary evaluation will be enrolled into the randomized trial. Inclusion criteria are: 18 years old, medical clearance to proceed with kidney or kidney-pancreas transplant evaluation, 7 days since date of initial transplant evaluation clinic appointment, and ability to provide informed consent. Exclusion criteria are: previously listed for transplantation, evaluation for liver-kidney transplant, or participation in another study to increase the likelihood of LDKT.

Historical Controls—The historical control group will include 350 kidney transplant patients who presented for initial transplant evaluation between January 1, 2011 and December 31, 2017. Using our Organ Transplant Tracking Record (OTTR) database, we will work sequentially beginning January 1, 2011 to identify historical controls matched 1:1 with our study sample on age (+/− 5 yrs.), race/ethnicity, and median household income by U.S. Census tract. Patients in the historical control group must meet the same inclusion/exclusion criteria as those patients enrolled in the trial.

Living Donors—We will recruit potential living kidney donors who initiate evaluation for kidney transplant candidates enrolled in the trial to complete a brief survey regarding concern about lost wages and the importance of possible wage reimbursement on decision-making about donation. Those who undergo donor surgery will be recruited to participate in an additional assessment as described below.

Screening and Recruitment

Kidney Transplant Candidates—The medical records of all patients referred for transplantation at our center are first screened by a transplant nurse coordinator and nephrologist. Patients who meet our preliminary transplant eligibility criteria are then scheduled for an initial appointment in our multidisciplinary transplant evaluation clinic. Approximately two weeks before their scheduled evaluation appointment, patients will be mailed a letter from the Principal Investigator (JRR) and Medical Director (MP) describing the study. During their clinic visit, patients will be approached by one of the investigators who will describe the study, confirm eligibility, answer all questions, and request study participation. Patients will be informed only that the two groups comprise two different maximum amounts of wage reimbursement, but not the specific dollar amounts. Patients who agree to participate will provide written informed consent and the Project Coordinator will then immediately randomize the patient into the trial. At this time, the patient will be informed of the maximum amount of lost wages reimbursement available for anyone who donates a kidney on their behalf. Patients will remain blinded to the reimbursement amount in the other group. Next, we will ask the patient to complete the baseline questionnaire assessment. Every effort will be made to enroll patients at the time of their multidisciplinary clinic appointment. However, patients who are not approached during clinic will be called by one of the study investigators within 48 hours to describe the study, answer questions, and obtain verbal consent if the patient is interested in study participation. The Project Coordinator will then randomize the patient, provide guidance on completing the baseline questionnaire assessment, and mail (or email) a copy of the written informed consent document.

Living Donors—All potential living kidney donors who contact the transplant center to initiate donation evaluation on behalf of a kidney transplant candidate enrolled in the trial will be informed by the donor nurse coordinator about the study and told that a member of the study team will contact them via telephone or email to provide additional study details. The Project Coordinator will contact each potential living donor within 48 hours of their initial inquiry to the transplant center, provide study information, explain eligibility criteria for lost wages reimbursement and the maximum amount based on the kidney transplant candidate's assigned group, refer them to the study website that provides details regarding reimbursement processes, and request participation in a brief survey. Survey completion is not required for lost wages reimbursement eligibility.

Usual Care

All enrolled kidney transplant candidates will receive usual LDKT education. Kidney transplant candidates at our center are informed during initial evaluation by the transplant nephrologist, surgeon, nurse coordinator, and social worker that LDKT is their best

treatment option and they are encouraged to discuss living donation with members of their family and social network. Patients are required to attend – with or without a caregiver – one 60-minute group-based transplant education session led by a transplant nurse coordinator. All patients receive a transplant education binder during their evaluation that includes information about all aspects of kidney transplantation, including LDKT, living donation, strategies for talking to others about donation, our transplant center website, and the NLDAC program. Kidney transplant candidates enrolled in the trial will again be given the NLDAC brochure at the time of study enrollment to ensure that they received it and have the most up-to-date eligibility information. Furthermore, they will be encouraged to discuss NLDAC with any potential living donors.

Potential living kidney donors who inquire about or are evaluated for donation on behalf of an enrolled transplant candidate also will receive usual donation education at our center. This includes an education session with a living donor nurse coordinator, access to our center's living donation website, the *Preparing for Your Kidney Donation* education binder, a pamphlet describing the National Kidney Foundation's living donation website (www.livingdonors.org), and a description of kidney paired donation. Our center's education binder describes potential direct and indirect costs of donation and contains detailed information about sources of potential financial assistance, including several non-profit organizations and NLDAC. Potential living donors are referred to the American Society of Transplantation's Live Donor Financial Toolkit (www.myast.org/patient-information/live-donor-toolkit), which guides them through a donation cost-estimation worksheet, and describes the need for donors to take time off work and how that may affect wages, fundraising strategies, and sources of financial assistance. Potential living donors who may meet NLDAC eligibility criteria for reimbursement of travel and subsistence expenses are asked to submit the required application documents to us, and we then obtain financial information from the intended kidney transplant recipient prior to submission to NLDAC.

Donor Recovery Lost Wages Reimbursement Intervention

Kidney transplant candidates will be informed that, in addition to the NLDAC program, their living donor may be eligible to receive reimbursement for wages lost during the donation recovery period – up to amount specified based on randomization. They will be given a study information sheet (and access to the study website) describing the wage reimbursement program, eligibility criteria, and application process to share with their potential living donors. It is possible that a potential living donor who initiates evaluation for a kidney transplant candidate in the study may not know about the wage reimbursement study. Therefore, at the time of study enrollment, kidney transplant candidates will consent to allowing the donor nurse coordinator and study team to inform all of their potential living donors about the study, their participation in it, and the potential for reimbursement of donor lost wages up to the maximum amount based on their randomized condition.

With guidance from our Living Donor Advisory Group and review of wage reimbursement policies and practices in other countries, we developed a framework of guidance and oversight, eligibility criteria, and application processes for wage reimbursement as part of this study. For both trial arms, wage reimbursement will occur for living kidney donors who

donate within 12 months of the transplant candidate's initial evaluation date. The application must be filed with the study team within the requisite time period, provide the required documentation, and meet eligibility criteria. Reimbursement will be restricted to lost wages following donation during the recovery period, up to 90 days post-donation. Living donors will be reimbursed only for lost wages that are documented by the employer or, if self-employed, supported by the last 2 years of income tax filings and self-report attestation. For those eligible for short-term disability through their employer, only lost wages not covered in the disability plan will be eligible for reimbursement. Reimbursement will be limited to lost wages not covered by any other entity. We will not require living donors to use paid vacation or paid medical leave as a condition of reimbursement of lost wages. Living donors without a valid social security number (or Individual Taxpayer Identification Number) will not be eligible.

An application for wage reimbursement must be filed by living kidney donors within 120 days after surgery. Once received, the application will be screened by the Project Coordinator, any missing information will be gathered, and the authorizing employer representative will be called to verify claimed lost wages, if necessary. The application review committee (Principal Investigator, one Co-Investigator, Project Coordinator, and a transplant social worker unaffiliated with the study) will review all completed applications, confirm eligibility criteria are met, and either recommend payment at or below the level requested by the living donor, based on additional information gathered from the employer, or deny payment.

Random Assignment

Kidney transplant candidates will be randomized 1:1 to the LW-1500 or LW-3000 arm, with stratification for race. The study biostatistician will prepare the randomization schedule, using permuted blocks of randomly varying size to limit predictability and imbalances in arm assignment throughout the study. Allocation will be concealed from the study investigators and research assistants conducting any questionnaire assessments. Kidney transplant candidates will be informed of their own group assignment immediately after enrollment, but will remain blinded to the other group's maximum amount of lost wages reimbursement.

Assessment Protocol

Primary Outcome—The primary outcome of the study is the occurrence (yes, no) of LDKT within 12 months after the patient's initial transplant evaluation date. Twelve months was selected as the endpoint because it provides sufficient time for enrolled transplant patients to identify potential living donors and for those potential donors to complete their evaluation and undergo surgery.

Secondary Outcomes—Secondary outcomes are: (a) occurrence (yes, no) of a living donor inquiry, (b) number of living donor inquiries, (c) occurrence (yes, no) of a living donor evaluation, and (d) number of living donor evaluations within 12 months of initial transplant evaluation. As in our previous studies^{39,40}, a living kidney donor inquiry is operationalized as a request for donation information by someone in the transplant

candidate's social network. The request may be directed toward any transplant team member – in person, by telephone, or via email. Donor evaluation is defined as completion of preliminary health screening or compatibility testing for which a preliminary donor eligibility determination has been made by the donor evaluation team. We will also track the number and percentage of potential living donors who then pursue the full evaluation and for whom a final donor eligibility determination is made.

In addition to these outcomes, we will assess the intervention's acceptability and impact. Table 1 summarizes these assessments and their timing for transplant patients. All kidney transplant candidates enrolled into the trial will complete an electronic (Research Electronic Data Capture, or REDCap, www.project-redcap.org), telephone, or paper-and-pencil baseline questionnaire assessment, based on patient preference, at time of study enrollment and again at 3 and 6 months following enrollment. These questionnaires were chosen to measure constructs found to be associated with pursuit of LDKT in prior studies, as well as potential covariates. Enrolled patients who receive a LDKT during the study will be asked to complete a brief questionnaire 3 months following transplantation. This post-LDKT assessment will measure perceived pressure on their living donor, LDKT decision stability (i.e., would make the same decision to pursue LDKT again), financial concerns about the living donor, and whether availability of wage reimbursement for their living donor made the decision to pursue LDKT easier.

As noted previously, all potential living kidney donors who contact the transplant center on behalf of a patient enrolled in the study will be informed about the study, the wage reimbursement program, and asked to complete a brief survey. The survey, which will be completed online (via REDCap), by mail, or by telephone with a research assistant, will assess financial concerns about donation and their relative importance on donation decision-making, donation ambivalence, and feelings of pressure to donate (Table 2). Additionally, those who donate a kidney on behalf of a patient enrolled in the study will be asked to complete a brief assessment 3 months post-donation to measure overall satisfaction with the donation experience, perceived pressure to donate, decision stability (i.e., would make the same decision to donate again), financial impact of donation, and whether the availability of wage reimbursement influenced the decision to pursue donation.

Reimbursement Metrics—We will collect several measures assessing interactions between the program and those who donated on behalf of a patient enrolled in the study. These measures include: (a) the number (and percentage) of living donors who submitted an application to the NLDAC program, (b) the number (and percentage) of living donors whose NLDAC applications were approved, (c) the amount of NLDAC funding received for post-donation costs, (d) the number (and percentage) of living donors who submitted an application to the study team for reimbursement of lost wages, (e) the number (and percentage) of living donors whose application for lost wages reimbursement were approved, and reasons for denial if any, (f) the amount of lost wages requested, approved, and reimbursed, (g) donor ratings about the acceptability and ease of the application process, and (h) time from application submission to approval to dispensation of funds.

Statistical Analysis, Power, and Sample Size Estimations

Preliminary analyses will examine (a) the underlying distributional properties of all outcome variables and covariates, (b) patterns of missing data, and (c) patterns of attrition. Regression diagnostics will be used to evaluate outliers, model assumptions, and influential observations. We will apply appropriate mathematical transformations to any variable whose distribution is found to not meet the underlying requirements of the statistical techniques being used. Selection of the appropriate transformation will be prioritized as follows: 1) satisfaction of the linearity assumption, 2) satisfaction of the homogeneity assumption, and 3) satisfaction of the normality assumption. Descriptive statistics will be calculated for all measures and variables. Data analyses will be sequential to first examine the primary outcome, secondary outcomes, tertiary outcomes, and outcome predictors. Also, the equivalence of random assignment of groups on baseline demographic and medical characteristics will be assessed using chi-square tests, ANOVAs, and Wilcoxon rank sum tests, as appropriate. If the groups differ on any characteristics, these variables will be used as covariates in the primary outcomes analyses.

For Aim 1 (test the effectiveness of offering reimbursement for living kidney donor lost wages on the LDKT rate in kidney transplant candidates), 2-sided 95% CIs for the difference in proportions between enrolled transplant candidates (combining LW-1500 and LW-3000) and matched historical controls will be calculated and Cochran-Mantel-Haenszel (CMH) tests will be computed, taking into account the stratification by race. CMH tests will be used to compare differences in proportions between LW (combined) and historical controls for other variables with a dichotomous outcome (i.e., donor inquiry, donor evaluation). We will also examine the distributions of time from transplant evaluation to LDKT for the combined LW groups versus the historical control group using Cox proportional hazards model, and compare the rates between the groups.

The study is powered based on a clinically meaningful proportional difference of 0.15 in LDKTs between the combined LW groups and the matched historical controls at the 12-month study endpoint. Annual LDKT rates fluctuate (+/-) 1% to 3% nationally and 3% to 10% at the center level. We believe that an absolute difference of 15% is beyond normal fluctuations and, therefore, clinically meaningful. A sample size of 350 per group (LW groups combined and matched historical controls) achieves >90% power to detect proportional differences between the two groups using CMH tests with continuity correction and a significance level of 0.05. Based on our previous studies and historical trends, we anticipate that ~10% of patients will have died, been removed from the waiting list, or transferred care to another transplant center by the 12-month endpoint. However, we will know the primary study outcome (i.e., LDKT occurrence) for 100% of enrolled patients.

For Aim 2 (examine whether offering reimbursement for living kidney donor lost wages reduces racial disparities in LDKT rates), separate regression models will be performed to evaluate the interaction between group (LW groups combined versus matched historical controls) and race, as follows: $Y = \alpha + \beta_1 X + \beta_2 Z + \beta_3 XZ + e$ where β_1 is the coefficient for group (X) to the outcome of LDKT occurrence (Y), when $Z=0$. β_2 is the coefficient for the moderator variable of race (Z) to the outcome of LDKT occurrence (Y), when $X=0$. e corresponds to the residual in the equation. β_3 will provide an estimation of the moderation

effect and simple regression slopes will be plotted. Similar models will be used to examine moderation effects of race on secondary outcomes (e.g., donor inquiry, donor evaluation). The current proportional difference in LDKT rate between white and minority patients at our centers is 0.12 (0.23 for whites – 0.11 for minorities), which is equivalent to the national proportional difference (0.13) and is statistically significant ($p < 0.001$). Using historical patterns of 50% of patients evaluated being racial minority at our center, we will achieve 80% power to detect change in proportional differences in LDKT rate by race/ethnicity (both LW groups combined), using CMH tests with continuity correction and a significance level of 0.05.

For Aim 3 (determine whether higher reimbursement amounts lead to higher LDKT rates), 2-sided 95% CIs for the difference in proportions between LW-1500 and LW-3000 groups for LDKT occurrence at the 12-month study endpoint will be calculated and CMH tests will be computed, taking into account stratification by race. CMH test will be used to compare differences in proportions between LW-1500 and LW-3000 for other variables with a dichotomous outcome (i.e., donor inquiry, donor evaluation). Using the Kaplan-Meier method we will also assess time-to-event endpoint to determine whether LW-3000 results in LDKT more rapidly than LW-1500.

DISCUSSION

Several design issues were considered and discussed by the research team. First, we decided to randomize transplant candidates rather than potential living donors. We have shown that concern about donor lost wages affects the transplant candidate's decision to discuss donation with others.¹⁰ Also, randomization of potential living donors is not scientifically or ethically justified. Contamination may occur, thus threatening internal validity, and transplant candidates or family members may place undue pressure to donate on those potential donors assigned to receive higher wage reimbursements. Second, including a contemporaneous no wage reimbursement comparison group in the RCT would be the most scientifically rigorous approach. However, we were unable to justify it ethically, after our donor advisory group, bioethicists, and institutional review board raised equipoise concerns. Third, the decision to examine two different amounts of lost wages reimbursement allows us to examine the threshold when wage reimbursement becomes more effective. Also, existing international policies on reimbursement of donor lost wages vary in maximum amount and there are no data on the relative effectiveness of these differing amounts to inform future policy discussions here in the United States.²¹ We chose \$1,500 and \$3,000 as the amounts to use in this study because published research shows that median lost wages ranges approaches \$3,000.^{7,8} Fourth, we restricted reimbursement of lost wages incurred during the post-donation recovery period because the financial burden for many donors is highest at this time.^{8,10} Nevertheless, we recognize that many potential living donors also incur expenses, including lost wages, during the donation evaluation process and support any future reimbursement mechanisms that include these pre-donation costs.⁴¹ Fifth, we considered restricting lost wage reimbursement to only those living donors who meet certain income thresholds. However, we chose not to use financial means testing to determine donor eligibility for reimbursement. We find the moral justification argument advanced by others to be very compelling.^{18–24} That is, the pursuit of financial neutrality for all donors, not only

for those who meet arbitrary financial guidelines, is morally just and defensible. Also, while financial loss may be proportionally higher for those with less income, it is likely that many potential living donors with household incomes that exceed NLDAC eligibility decide not to donate due to concerns about income loss. Thus, setting a financial means threshold for eligibility would be arbitrary and not based on the actual financial burden experienced by the donor.

In summary, LDKT offers the best outcomes for adults with ESRD, but this treatment requires healthy and willing living donors. Living donation has declined in the U.S., particularly among ethnic/racial minorities and low-income adults. This may be due, in part, to costs incurred by donors, which may affect the willingness of transplant candidates to pursue LDKT and of potential living donors to actually donate. There are now ample data demonstrating that living donors incur large costs. Existing programs may reimburse some of these costs, but lost wages are not covered by NLDAC. The transplant community has called upon researchers to investigate innovative strategies to attenuate financial disincentives. This study will be the first to empirically examine the impact of offering lost wages reimbursement for donors on LDKT rates, and whether such wage reimbursement reduces the racial disparity in LDKT rates. As such, findings from this study have very high potential to influence policy, clinical practice, LDKT access, and known income and racial disparities in kidney transplantation. If study hypotheses are supported, we will have established scientific evidence for how reimbursement of donor lost wages affects LDKT rates and disparities.

Acknowledgments

This study described herein is supported by Award No. R01DK114877 from the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK). The content is solely the responsibility of the authors and does not necessarily represent the official views of the NIDDK or the National Institutes of Health. The NIDDK had no involvement in the study design; the collection, analysis and interpretation of data; the writing of this manuscript; or the decision to submit the manuscript for publication.

Abbreviations

LDKT	Living Donor Kidney Transplantation
NLDAC	National Living Donor Assistance Center

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Table 1

Kidney transplant candidate and recipient assessment protocol and timing

Constructs	Description	Kidney Transplant Candidate				Kidney Transplant Recipient	
		BL	3 mos.	6 mos.	12 mos.	3 mos. post-transplant	
Pre-transplant Characteristics	Transplant indication, prior transplant, dialysis status and duration, inactive waitlist time, calculated panel reactive antibodies	x	x	x			
Quality of Life	Health-related quality of life (20 items)						
Healthcare System Distrust	Healthcare system distrust (9 items; 5-point Likert scale)	x	x	x			
Subjective Literacy and Numeracy	Perceived health literacy and ability/preferences for numerical information (10 items)	x					
LDKT Knowledge	LDKT knowledge (23 items, true-false)	x					
LDKT Concerns	Concerns about pursuing LDKT (23 items; 5-point Likert scale)	x					
LDKT Self-efficacy	Self-efficacy about pursuing LDKT (16 items, 5-point Likert scale)	x	x	x			
LDKT Willingness	Willingness to talk to others about kidney donation (1 item; 7-point Likert scale)	x	x	x			
LDKT Readiness	Stage of readiness to pursue LDKT (1 item; 5 stages)	x	x	x			
LDKT Ambivalence	Uncertainty or doubt about pursuing LDKT (1 item; 5-point Likert scale)	x	x	x			
LDKT Decision-making	Degree to which patient feels they can make fully informed decision about LDKT (4 items; 4-point Likert scale)	x	x	x			
LD Discussion with Others	Whether or not patient has discussed donation with members of social network (8 questions; yes-no)	x	x	x			
Financial Concerns	Concerns about financial impact on potential living donors (3 items)	x	x	x			
Kidney Transplant Outcomes	Receipt and type of transplant, time from study enrollment to transplant, number of potential donor inquiries and evaluations				x		
LDKT Decision Stability	Would make same decision again to pursue LDKT (1 item)					x	
Post-LDKT Financial Questions	Concerns about financial impact on donor, provision of financial support to donor, impact of lost wages reimbursement on LDKT decision (6 items)						x

Table 2

Living kidney donor candidate and actual donor assessment protocol and timing

Measure	Description	Living Donor Candidate	Actual Living Donor
		At time of inquiry or evaluation initiation	3 mos. post-donation
Demographic Characteristics	Age, sex, race, ethnicity, annual household income, employment status, marital status, education, health and life insurance, and relationship to transplant candidate	x	
Subjective Literacy and Numeracy	Perceived health literacy and ability/preferences for numerical information (10 items)	x	
Donation Ambivalence	Uncertainty or doubt about pursuing LDKT (2 items; 5-point Likert scale)	x	
Donation Decision-making Scale	Degree to which potential donor feels they can make fully informed decision about donation (4 items; 4-point Likert scale)	x	
Financial Concerns Scale	Concerns about financial impact of donation (4 items)	x	
Donation Satisfaction	Overall satisfaction with donation (1 items; 5-point Likert scale)		x
Donation Pressure	Perceived pressure to donate (2 items)		x
Donation Decision Stability	Would make same decision again to donate (1 item)		x
Post-donation Financial Questions	Donation-related direct and indirect expenses incurred, receipt of financial support, impact of lost wages reimbursement on donation decision (7 items)		x