



NATIONAL KIDNEY REGISTRY

FACILITATING LIVING DONOR TRANSPLANTS

April 29, 2020

Frank Holloman
Director, Division of Transplantation
Healthcare Systems Bureau - Health Resources and Services Administration
5600 Fishers Lane, Room 08W63 Rockville, MD 20857

RE: HRSA-2020-06628

Dear Mr. Holloman:

As a living kidney donor myself, I applaud HRSA's interest in reimbursing travel and lodging expenses related to living kidney donation, but must point out that these HRSA funds are being poorly spent. We are hopeful that this public comment process will provide useful information that will allow HRSA to reform its current funding process and better protect living donors from the costs of giving the gift of life. HRSA's current program for reimbursing travel and lodging expenses (NLDAC) is **six times more expensive** than the NKR's travel and lodging program. HRSA must open up funding for travel & lodging reimbursement to a competitive bidding process so that all living donors have the opportunity to be reimbursed for travel and lodging expenses, without income limits and at a much lower cost to taxpayers.

The National Kidney Registry (NKR) is the largest paired exchange program in the world and facilitates approximately 1,000 kidney transplants per year across nearly 100 transplant centers in the United States. The NKR is also the leading provider of comprehensive living kidney donor protections in the United States. Our Donor Shield program protects approximately 25% of all U.S. living kidney donors. In other words, the NKR is already eliminating disincentives to living donation efficiently and on a massive scale - much larger than the current HRSA funded program which addresses only one of the seven living donor disincentives addressed by the NKR's Donor Shield program. The Donor Shield protections go far beyond the reimbursement of travel and lodging and the NKR donor protections are already available to donors at roughly half of all U.S. transplant centers.

Not only are the NKR donor protections helping patients realize life-saving transplants by increasing the number of transplants, and not only is this right thing to do for generous living donors who give the gift of life, but these donor protections have the potential to **save the federal government \$10 billion dollars** over the next decade.

Based on our actual experience eliminating disincentives, we can achieve 100% adoption of the NKR's Donor Shield protections if we have HRSA's full support. A 100% adoption rate for Donor Shield will increase living donor transplants in the U.S. by at least 15% which equates to approximately **1,000 additional living donor transplants per year**. Life expectancy on dialysis for a patient that can qualify for a transplant is about 15 years, and dialysis related costs are about \$90,000 per year. The savings for one additional living donor transplant is about \$1.2 million (15 years x \$90K x present value factor) less the cost of the transplant (\$200,000) which yields a net savings to our government of \$1 million dollars for each additional transplant. 1,000 additional living donor transplants per year delivers \$1 Billion in savings (present value) annually. Over 10 years, our government can save \$10 Billion dollars by fully supporting the NKR's comprehensive Donor Shield protections.

With HRSA's full support, the NKR can provide Donor Shield protections (described below along with other NKR programs that are eliminating important disincentives to living donation) to all living donors in the United States by the end of 2020. The cost to achieve the \$10 Billion in savings is approximately \$3,000 per transplant, or an inconsequential \$21 Million per year. **This equates to a return on investment of over 10,000%**. Imagine the enthusiasm of an investor that could get a Billion dollar return on a \$21 Million dollar investment while saving/improving lives.

Donor Shield (no income restrictions for eligibility)

- 1) Lost Wage Reimbursement: up to 4 weeks and up to \$1,500/week
- 2) Travel & Lodging Reimbursement: up to \$2,000
- 3) Donation Life Insurance: \$500,000 principle amount
- 4) Donation Disability Insurance: \$1,500/ week up to 52 weeks reimbursed
- 5) Legal Support: Unlawful termination & health insurance issues
- 6) Coverage for Uncovered Complications
- 7) Lost Wages and Travel/Lodging Reimbursement for Post-surgery Complications

Travel & Lodging Reimbursement: Major Problems with HRSA's program

While raising the income cutoff from 300% to 350% will help a few additional living donors, there are serious problems in using standard income restrictions for reimbursing donor costs.

- 1) In 2018, the median household income by region ranged from \$44,097 to \$85,203. Using a standard cutoff for the entire country is unfair to donors living in high cost regions.
- 2) The NLDAC program requires both the donor and the recipient to be means tested. This forces a donor seeking financial support to have an awkward conversation with the recipient and raises ethical issues related to donor-recipient financial conflicts.
- 3) The NKR's Donor Shield program has no income restrictions and is significantly less costly than the NLDAC travel & lodging reimbursement program, calling into question why any income cutoff or recipient means testing is needed.

Since January 9, 2019, the NKR has reimbursed 215 donors for travel & lodging costs at an average of \$856 per transplant with a \$2,000 cap on reimbursements and no income cut-off for eligibility. Only 13% of the NKR requests hit the \$2,000 cap. According to published research, HRSA's NLDAC travel and lodging reimbursement program has a cost of approximately \$5,082 per transplant (\$6.76M/1330 transplants). This includes \$2,772 for donor travel and lodging reimbursement and \$2,310 in overhead ¹ (Exhibit 1). To put this massive cost variance into perspective, if NKR were to be awarded a \$5,000,000 HRSA grant to provide donor travel & lodging reimbursement, NKR could reimburse six times as many donors, 5,841 donors as compared to 984 for NLDAC. Assuming an average of 6,000 living donors per year, and a 20% utilization rate (NKR's current utilization rate) the NKR could offer travel and lodging reimbursement for all U.S. living donors for the next 4-5 years.

¹ Mathur, Amit K.; Xing, Jiawei; Dickinson, David M.; Warren, Patricia H.; Gifford, Kimberly A.; Hong, Barry A.; Ojo, Akinlolu; Merion, Robert M. (07 2018). "Return on investment for financial assistance for living kidney donors in the United States". *Clinical Transplantation*. 32 (7): e13277. doi:10.1111/ctr.13277. ISSN 1399-0012. PMID 29740879

Below are programs offered by the NKR that, in addition to the Donor Shield program, eliminate important disincentives to living kidney donation. HRSA should be supporting these programs so that living donors are better protected.

Remote Donation

To date, 61 of the NKR Member Centers have joined the Remote Donation Network which allows donors to undergo workup and surgery at a center near their home when their intended recipient is at a hospital in a distant city. This dramatically lowers the cost of the donor's travel & lodging and makes the donation process much easier for the donor – they can recover at their home as opposed to recovering in a hotel in a distant city. The same GPS technology used to safely ship living donor kidneys for NKR swaps (over 3,000 without failure) is used to reliably transport the remote donor kidneys to the recipient center. Remote donation significantly lowers the donor's travel & lodging costs.

Family Voucher

The Family Voucher program allows donors to donate to a stranger (start a chain) and provide up to 5 vouchers for family members in the unlikely event that they may need a kidney transplant in the future. I donated my kidney in 2015, starting an 8-deep chain, while providing a voucher for my daughter, who received a kidney transplant in 2007 and is doing well post-transplant. I would not have donated my kidney if not for the family voucher program.

Standard Voucher

The Standard Voucher program allows donors to undergo surgery when it is convenient for them and generate a voucher for their friend or family member that is in imminent need of a transplant. This is especially useful when the donor is the recipient's caretaker or when the donor has an inflexible work schedule (e.g. in the military and has limited leave time, teacher, judge, etc.). This program also allows donors to help more than one person in need of a transplant by starting a chain, while providing a voucher to their intended recipient.

Prioritization for LD kidney

All living donors in the U.S. are prioritized for a **deceased** donor kidney through the OPTN in the unlikely event they ever need a transplant. All donors that donate in an NKR swap are prioritized for a **living** donor kidney via the NKR in the unlikely event that they ever need a kidney transplant. Prioritization for a living donor kidney is important to donors because living donor kidney transplants have better outcomes and generally last 2-3 times longer than deceased donor kidney transplants.

Summary

NKR is already providing comprehensive living donor protections, including travel and lodging reimbursement, efficiently and on a massive scale. These donor protections go far beyond the narrow travel & lodging reimbursement program currently funded by HRSA and are already available to donors at roughly half of all transplant centers in the United States. HRSA's plans are unwittingly hurting living donors by the ongoing funding and promotion of an expensive and inferior travel & lodging reimbursement program.

As a donor myself, I experienced firsthand many of the disincentives to living donation. These disincentives are not theoretical; they are very real. HRSA needs to do more to help eliminate disincentives to living donation and we urge HRSA to partner with the NKR to bring much needed comprehensive donor protection to every living donor in the United States by the end of 2020. In doing so we can do the right thing for donors, increase the number of life-saving transplants and put our government on a path to save \$10 billion dollars over the next decade.

Sincerely,

A handwritten signature in blue ink, appearing to read 'GH', with a long horizontal stroke extending to the right.

Garet Hil
Founder & CEO
National Kidney Registry
Living Kidney Donor

Exhibit 1

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ORIGINAL ARTICLE

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Return on investment for financial assistance for living kidney donors in the United States

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Abstract

Background: The National Living Donor Assistance Center (NLDAC) enables living donor kidney transplants through financial assistance of living donors, but its return on investment (ROI) through savings on dialysis costs remains unknown.

Methods: We retrospectively reviewed 2012-2015 data from NLDAC, the United States Renal Data System, and the Scientific Registry of Transplant Recipients to construct 1-, 3-, and 5-year ROI models based on NLDAC applications and national dialysis and transplant cost data. ROI was defined as state-specific federal dialysis cost minus (NLDAC program costs plus state-specific transplant cost), adjusted for median waiting time (WT).

Results: A total of 2425 NLDAC applications were approved, and NLDAC costs were USD \$6.76 million. Median donor age was 41 years, 66.1% were female, and median income was \$33 759; 43.6% were evaluated at centers with WT >72 months. Median dialysis cost/patient-year was \$81 485 (IQR \$74 489-\$89 802). Median kidney transplant cost/patient-year was \$30 101 (IQR \$26 832-\$33 916). Overall, ROI varied from 5.1-fold (1-year) to 28.2-fold (5-year), resulting in \$256 million in savings. Higher ROI was significantly associated with high WT, larger dialysis and transplant costs differences, and more NLDAC applicants completing the donation process.

Conclusions: Financial support for donor out-of-pocket expenses produces dramatic federal savings through incremental living donor kidney transplants.

KEY WORDS

financial support, kidney transplantation, living donor

1 | INTRODUCTION

Living donor kidney transplant provides a significant survival benefit for transplant recipients, small long-term risks to donors, and value to the health care system. From the perspective of the Centers for Medicare & Medicaid Services (CMS) and other payers, the availability of a living kidney donor for a patient on dialysis represents an opportunity for major financial savings.¹ According to the United States Renal Data System (USRDS), the average annual cost for hemodialysis is approximately \$80 000 per year while the average

costs to maintain a transplant patient are approximately \$30 000 per year.² These savings are magnified in areas with prolonged kidney transplant waiting times.

Living donation rates have been falling since 2004 in the United States, which also reduces the overall cost savings associated with transplantation for the end-stage renal disease (ESRD) population. The financial cost incurred by living donors is thought to be a leading contributor to this decline. While medical costs for living donors are covered by recipient insurance, potential donors are subject to financial disincentives to donation, such as

the cost of travel to the transplant center, subsistence expenses in the evaluation process, and wages lost during and after evaluation and donation.^{3,4} Reimbursement of these costs is legal under the National Organ Transplant Act⁵ and does not represent “valuable consideration.” The National Living Donor Assistance Center (NLDAC) is a program funded by the U.S. Health Resources and Services Administration (HRSA) that provides financial means-tested support for travel and subsistence costs for donors.⁶ It has provided more than \$10 million in support to thousands of living organ donors.

The National Living Donor Assistance Center support enables incremental living donor kidney transplants. Among donors who received NLDAC funds, 75.6% stated that they would not have been able to donate a kidney without financial assistance from the program.⁷ Their recipients would have therefore stayed on dialysis and waited for a kidney transplant from a deceased donor. The differences in per-patient annual costs between maintenance dialysis and kidney transplantation is approximately \$50 000.¹ The return on investment (ROI) for the federal funding of the NLDAC program is unknown; differences in dialysis costs and variation in the waiting time for deceased donor kidney transplants across the USA may alter the ROI. In this analysis, we aim to quantify the return on the federal NLDAC investment. By enabling living donor transplants, the NLDAC program theoretically subsidizes a decline in federal spending over time by converting a dialysis patient into a transplant patient. With growing attention to CMS cost containment, and disproportionate CMS spending attributable to ESRD, understanding the ROI for interventions that reduce dialysis use is paramount. We hypothesized that the ROI for federal funds distributed by NLDAC is substantial based on the large difference in per-patient annual costs of maintenance dialysis versus kidney transplantation and especially so in states with longer waiting times for deceased donor kidney transplants and higher dialysis costs. With growing attention to value of ESRD care, patients, providers, and payers all have a significant interest in the implementation of programs that reduce cost and add clinical benefit to the renal failure population. In-depth analysis of the variation in NLDAC ROI presents an opportunity to inform stakeholders on the opportunities to improve and optimize the value of this type of program.

2 | METHODS

2.1 | Eligibility for financial assistance from NLDAC

The National Living Donor Assistance Center operates as a payer of last resort for travel and subsistence costs related to predonation evaluation, living donor nephrectomy, and follow-up care for up to 2 years after living donation. Applications for the NLDAC program are filed by transplant centers on behalf of a potential living donor. Potential living donors are eligible for NLDAC support based on means testing, based on both recipient and donor income, as recipients are legally permitted to pay the travel and

subsistence costs for their donors. Eligibility criteria include having earnings below 300% of the federal poverty line and demonstration of financial hardship. NLDAC support is capped at \$6000 per donor, and funds are distributed via controlled-value cards and can be applied to certain vendors for paying travel expenses and purchasing food and other necessities related to a trip to a transplant center.

2.2 | Conceptual model of return on investment for NLDAC financial assistance

The ROI model calculation at a given time point is based on the ratio of spending on dialysis less the costs of NLDAC and kidney transplantation to NLDAC program costs.

The equation is $(ROI)_{time} = \frac{[Dialysis\ Costs - (Transplant\ Costs + NLDAC\ costs)]_{time}}{[NLDAC\ Costs]_{time}}$. This equation allows the calculation of federal savings on dialysis savings related to use of NLDAC through incremental living donor transplants. Additionally, aside from its numerical determinants such as differences in dialysis costs, ROI may be sensitive to dialysis waiting time, local transplant program competition, or other factors.

2.3 | Data sources

The National Living Donor Assistance Center application and financial records from September 2012 to August 2015 were used to capture programmatic costs, including costs paid directly to potential kidney donors as well as administrative costs. Variation in time to deceased donor kidney transplant data by transplant center was obtained from the Scientific Registry of Transplant Recipients (SRTR). CMS costs for dialysis and transplantation were obtained from the USRDS by state. For dialysis and transplantation costs, the USRDS provides aggregated estimates of mean annual per-patient costs. For transplantation, the costs of the transplant procedure and associated “year one” costs after the procedure are averaged over the entire post-transplant period to provide an estimate of average cost per-patient-per-year for kidney transplantation. The costs for an individual kidney transplant recipient or ESRD patient may obviously vary, but the intent of the study was to provide a global view of these costs.

2.4 | Analytic assumptions

The analytic assumptions used to model ROI are summarized in Table 1. The ability to estimate a conservative return on investment from the NLDAC program is predicated on assumptions about costs of dialysis, kidney transplantation, and timing of when patients receive deceased donor and living donor kidney transplants. Patients approved for kidney transplantation have multiple possible trajectories, with each outcome representing a competing risk. These outcomes include living donor kidney transplant, deceased donor kidney transplant, death, inactivation, or removal from kidney transplant waiting lists. These ROI calculations assumed that living

TABLE 1 Analytical assumptions of a model to calculate return on investment of federal funds to the national living donor assistance center through incremental living donor kidney transplants

#	Assumptions
1	Living donors came forward to recipients within the first year of wait-listing for kidney transplantation
2	For the recipients of NLDAC-enabled live donor transplants, we assumed that there were no other potential compatible living donors
3	For deceased donor kidney transplantation, we excluded candidate dialysis waiting time prior to wait-listing, as dialysis time is equivalent to waiting list time in the current allocation system
4	Patients with waiting time credit were less likely to pursue living donor transplant
5	Waiting time to deceased donor transplant was at least the median waiting time at the candidate's transplant center.
6	The rate of graft failure and return to dialysis within 5 y of live donor transplant is negligible
7	NLDAC costs were ascribed to the first year of waiting time and do not increase for subsequent years
8	Dialysis costs were based on the average state-specific per-patient annual dialysis costs as reported by United States Renal Data System
9	Transplant costs were based on the average state-specific per-patient annual transplant costs, where the costs of the procedure is aggregated across all years of transplant

donors came forward to recipients within the first year of wait-listing for kidney transplantation. For the recipients of NLDAC-enabled live donor transplants, we assumed that there were no other potential compatible living donors. For deceased donor kidney transplantation, we excluded candidate dialysis waiting time prior to wait-listing, as dialysis time is equivalent to waiting list time in the current allocation system. We assumed that patients with waiting time credit did not pursue living donor transplant. We also assumed that waiting time to deceased donor transplant was at least the median waiting time at the candidate's transplant center. Based on clinical data, we assumed recipients of living donor transplants had no graft failures within 5 years of transplant and had no return to dialysis during this period. NLDAC costs were ascribed to the first year of waiting time and do not increase for subsequent years.

Based on survey data of prior cohorts of living donors who have used the NLDAC program, 75.6% (n = 1453) of survey respondents agreed with the statement, "The NLDAC program made it possible for me to donate an organ." We applied an adjustment factor of 0.756 to ROI calculations to focus the estimate on incremental transplants that would not have otherwise occurred. We also conducted a sensitivity analysis to understand how ROI changes based on the proportion of donors that would not have been able to come forward without NLDAC support.

Applications accrued during the study period were used to create ROI projections. We calculated ROI at 1, 3, and 5 years from the time of NLDAC funds distribution. Transplant and dialysis cost variation were also derived from state-level data. Cost data were derived from de-identified population-level summary reports and internal NLDAC data.

2.5 | Modeling geographic variation in ROI

Based on our hypothesis and conceptual model of ROI, we aimed to determine the greatest predictors of geographic variation. We calculated state-specific ROIs based on NLDAC applications accrued from programs within the state, and state-specific dialysis and transplant costs, at 1, 3, and 5 years after the accrual period. We tested associations with state-specific dialysis costs, median waiting time to deceased donor transplant within the state, as well as local transplant program competition. We tested the association between dialysis and transplant costs by state using Pearson's correlation. As a measure of local competition, we used the Herfindahl-Hirschmann Index (HHI) calculated for each state. HHI is an established econometric indicator used in health care and other industries⁸ and has been applied by Halldorson et al⁹ in transplantation. The HHI measures the degree of kidney transplant market share controlled by a transplant center. State-specific HHI was calculated as the sum of the squares of market share for all kidney transplant centers within the state. Center market share in a given state was defined as the proportion of kidney transplants performed at a center within that state during the NLDAC application accrual period. High HHI values indicated low competition, whereas low HHI values indicated high competition. These variables were evaluated with simple and multiple linear regression models to calculate the effect of these covariates on ROI at each time point.

Transplant and dialysis cost variation were derived from state-level data. Cost data were obtained from de-identified population-level summary reports and internal NLDAC data. The study was exempt from IRB approval based on utilization of publicly available data (USRDS) for creation of ROI projections, and as described in

TABLE 2 Profile of NLDAC donors in study cohort (n = 2425)

	NLDAC donor
Age (median, y)	41
Female sex (% , n)	1603 (66.1%)
White race (% , n)	1896 (78.2%)
Annual income (median \$)	\$42 510
Average NLDAC spending (median \$)	\$2071

the “Public Benefit and Service Program” provisions of 45 CFR 46.101(b)⁵ and HRSA Circular 03 for SRTR data, and an existing IRB exemption issued by HRSA for utilization of NLDAC data. Statistical evaluations were conducted using SAS v9.4 (Cary, NC).

3 | RESULTS

From September 1, 2012 to August 31, 2015, NLDAC approved 2425 applications and 1330 went on to donate. Median NLDAC spending was \$1814 per applicant and \$2772 for actual donors. Donors were middle aged (median age 41 and 40 for all applicants and actual donors, respectively), predominantly female (66.1% and 67.2%, respectively), and of white race (78.2% and 79.6%, respectively). Median applicant annual household income reported to the program was \$33 759, which was slightly lower than that among actual donors (\$36 904). Table 2 summarizes these financial data. Figure 1 demonstrates the progression toward donation of NLDAC participants after application approval.

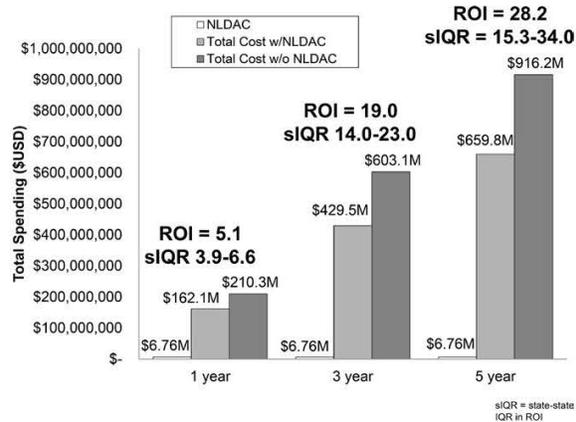


FIGURE 2 Projected return on investment for living donor financial assistance relative to U.S. dialysis and transplant costs. ROI from the NLDAC program is calculated here based on federal spending for dialysis and kidney transplantation, with and without the NLDAC program costs. NLDAC costs are derived from the initial application accrual period and are held constant through the projections over time. In the first year, investment in NLDAC produces \$48.2 million in savings, representing a 5.1-fold ROI overall. Notably, this ROI varied across states, from 3.9-fold to 6.6-fold. At 3 y, the ROI was 19-fold overall (state-state ROI IQR 14.0-23.0), producing \$173.6 million in savings. At 5 y, NLDAC investment produces \$256.4 in savings, representing a 28.2-fold return on investment, which ranged up to 34-fold at the 75th percentile of U.S. states

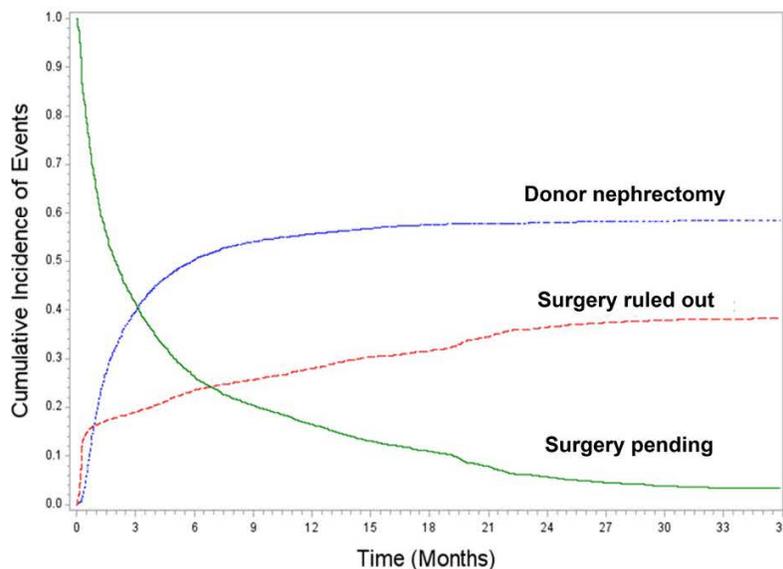


FIGURE 1 Trajectory of 2425 NLDAC applicants as potential kidney donors. In the application accrual period of the study cohort, 2425 applications were submitted to NLDAC for financial assistance. The plot shows the estimated cumulative incidence of 3 outcomes using a competing risk model to provide an estimated probability of donor nephrectomy, rule out of a potential donor related to center criteria, or potential donors continuing in the evaluation process (Surgery pending). Of these, 1330 NLDAC applicants underwent donor nephrectomy, representing 51.3% of approved applications. At the termination of application accrual period, 679 of NLDAC applicants had been ruled out for donor nephrectomy, and 397 applicants had surgery pending

3.1 | Dialysis cost, transplant cost, and waiting time data

Dialysis and transplant costs varied significantly by geography. According to the USRDS, median annual per-patient dialysis cost across the USA was \$81 485 in 2011, which varied by 2.2-fold across states (IQR \$74 489-\$89 802). Median annual per-patient kidney transplant cost was \$30 101, which varied by 3.2-fold across states (IQR 26 832-\$33 916). Based on median cost differences between dialysis and kidney transplant maintenance, an incremental living donor transplant saves approximately \$51 384 per patient per year. Waiting times for deceased donor transplant vary significantly in the United States based on donation service area, with overall median waiting time greater than 5 years. Median waiting time was >72 months for 43.6% of NLDAC applicants based on donation service area.

3.2 | Return on investment

Figure 2 demonstrates the overall projected ROI at 1, 3, and 5 years after NLDAC investment. **Total NLDAC costs during the application accrual period were \$6.76 million**, which represents 3.2% of the estimated 1-year spending on dialysis and transplant in the absence of the NLDAC program (\$210.3 million). The magnitude of ROI increased from 5.1-fold at 1 year to 28.2-fold at 5 years after initial

NLDAC investment. The overall projected savings at 5 years was \$256.2 million. Importantly, 75% of NLDAC donors stated that they would not have been able to donate without NLDAC support. In a sensitivity analysis evaluating ROI based on the variation in the proportion of donors who would not have donated without NLDAC support, NLDAC provided positive ROI on federal spending for dialysis even if as many as 90% of NLDAC donors would have donated their kidneys even if NLDAC support were absent (Table S1).

ROI varied significantly across U.S. states. Figure 3 shows three maps of the USA, with the NLDAC-associated savings per patient by state at 1, 3, and 5 years. Over 5 years, the absolute variation in savings increased, with some states achieving higher cost savings over time compared to others. While eight states had stabilization of savings at 3 years, 10 states were projected to save more than \$120 000 per patient over 5 years following the NLDAC investment. Table 3 demonstrates these latter 10 states, the donation service areas (DSAs) within those states, and their associated waiting times to deceased donor kidney transplant based on SRTR data. Each state has at least one DSA with waiting time >72 months, and eight of 10 had dialysis costs higher than or at the national average.

Univariate geographically based predictors of ROI, shown in Figure 4, demonstrate the state-level predictors of ROI from NLDAC at 1, 3, and 5 years. In multivariable analysis, state-level dialysis cost was the only independent predictor of ROI in the first 3 years after

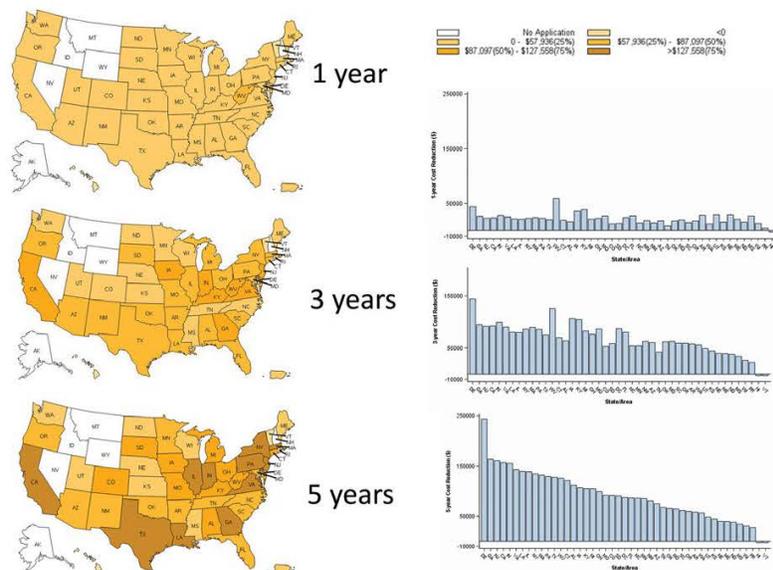


FIGURE 3 Geographic variation in projected return on investment for living donor financial assistance in the United States over time. This figure demonstrates nationwide differences in projected cost savings in dialysis and transplant costs per patient associated with the initial NLDAC investment over time. At 1 y, 43 of 50 states had median savings of \$20 814 per patient based on NLDAC investment and origin of applications, and West Virginia had savings between \$57 936 and \$87 097. At 3 y, the distribution of shading changed across the U.S. Relatively darker shaded states experienced greater savings per patient, with median savings of \$62 795 per patient (IQR \$53 067-\$86 489). All states with transplant programs submitting NLDAC applications were at least in the 2nd quartile of savings, with several states projected to have per-patient savings in the 3rd quartile (between \$88 645 and \$124 781) or the 4th quartile (>\$124 781). At 5 y, there was significant diversity in cost savings across the U.S. Median savings were \$87 097 per patient (IQR \$57 936-\$127 557). Twelve states were projected to have >\$127 557 in savings per patient (darkest shade). Four states reached maximum per-patient savings at 3 y

NLDAC investment ($\beta = 3.76$, 95% CI: (1.96, 5.56) and $P = .0002$). By 5 years, deceased donor transplant waiting time and dialysis cost were each significant predictors of ROI ($\beta = 3.77$, 95% CI: (2.16, 5.38) and $P < .0001$; $\beta = 4.40$, 95% CI: (1.79, 7.01) and $P = .0019$; respectively). While there was a trend over time suggesting that more within-state transplant program competition was associated with higher ROI, HHI was not a significant predictor of the ROI for the NLDAC program at any time point.

4 | DISCUSSION

Financial barriers are a common deterrent to living organ donation,² and only a few resource-limited programs have been designed to help defray otherwise nonreimbursed costs for living donors. The

financial impact of these programs has heretofore been unknown. The NLDAC program is the only federally funded program that assists impoverished living donors.⁶ Based on our analysis, NLDAC has provided a large ROI compared to the total costs of other renal replacement therapies. Based on 36 months of application accrual, we demonstrated a 28-fold return on each dollar invested in the program at 5 years, resulting in more than \$256 million in estimated savings. As CMS is the primary payer for dialysis and kidney transplant services in the USA, this represents major savings in health care spending over time.

The NLDAC ROI reflects an earlier transition from higher cost dialysis therapy to lower cost transplant maintenance therapy. Of the 2425 approved NLDAC applicants studied here, 1330 have donated a kidney. These NLDAC donors had median annual incomes of \$36 904, which corresponds to about 300% of the 2016 federal

TABLE 3 Dialysis costs and deceased donor waiting time in U.S. States with Highest ROI at 5 y from NLDAC Investment

State	State per-patient annual dialysis cost (\$)	Dialysis cost difference (vs National median annual dialysis cost = \$81 485)	Donation service area code	Median kidney waiting time (mos)
Delaware	\$85 741	\$4256	PADV	>72
Georgia	\$79 004	\$(2481)	GALL	>72
			ALOB	>72
			TNDS	54
New Jersey	\$106 521	\$25 036	NJTO	>72
			PADV	>72
California	\$96 278	\$14 793	CAOP	>72
			CASD	>72
			CADN	>72
			CAGS	>72
Indiana	\$89 802	\$8317	INOP	>72
			KYDA	32
			OHOV	>72
			ILIP	>72
Virginia	\$81 485	\$-	VATB	>72
			DCTC	42
			NCNC	54
			TNDS	54
Louisiana	\$80 815	\$(670)	LAOP	>72
Illinois	\$90 981	\$9496	ILIP	>72
			MOMA	32
			WIUW	20
New York	\$98 353	\$16 868	NYAP	48
			NYFL	>72
			NYRT	>72
			NYWN	>72
			PATF	48
Massachusetts	\$106 523	\$25 038	MAOB	48
			CTOP	>72
			NYAP	48

poverty level for a single person household, and used an average of \$2772 from NLDAC for travel and subsistence costs through all phases of the donation process. In exchange for this small amount of support to NLDAC applicants, the projected 5-year reduction in total renal replacement therapy cost was \$228 574 per NLDAC donor. As 75.6% of NLDAC donors stated that they could not have donated without the travel and subsistence support from the program, it is clear that NLDAC played an important role in facilitating incremental transplants. The NLDAC program was used by more than 9% of living donor transplants in the USA in 2015, highlighting the importance of this program to living donor transplantation in the USA.¹⁰ Modest expansion of the program would potentially increase the number of living donors assisted and still retain significant cost savings overall.

The National Living Donor Assistance Center program ROI varied across the USA and over time horizon. Underlying the variability in ROI is the broad range of state-level dialysis costs, which was evident within 1 year of NLDAC participation. By the 5-year time point, median waiting time for deceased donor transplant had an important and statistically independent association with ROI. These findings suggest that public and private payers, as well as

other stakeholders, could develop new donor financial assistance programs or seek strategic expansion of existing programs. Based on these data, maximal financial gains could be achieved by targeting their efforts geographically to those areas of the country with the highest dialysis cost and longest transplant waiting times. This strategy is highly relevant to current policy discussions that have touted the need for value-based care programs in high-cost health services, including ESRD care.³⁻⁶

Our ROI estimates likely underestimate the true financial savings of the NLDAC program. We were unable to account for the financial benefits to the system of another patient receiving the deceased donor kidney transplant that was obviated by the NLDAC-enabled living donor transplant. We also did not include financial benefits that recipients drive through return to work, prevention of job loss or by reducing disability payments related to an ESRD diagnosis. Additionally, these ROI calculations do not include private payer figures in the analysis, whose spending on dialysis is higher compared to CMS.⁷ In this context, the ROI identified here likely undervalues how much NLDAC and programs like it benefit the system overall.

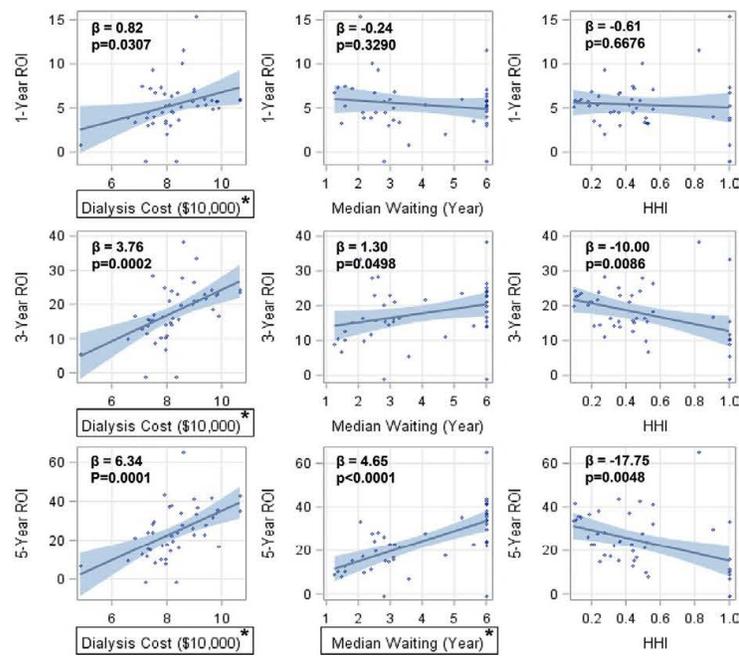


FIGURE 4 Predictors of state-level return on investment for living donor financial assistance. These nine panels demonstrate the respective relationships between dialysis costs, median waiting time to deceased donor kidney transplant, and the Herfindahl-Hirschmann Index (HHI) and the return on investment for living donor financial assistance. Each row represents a state-level ROI model at either 1, 3, or 5 y. Each panel is the result of a univariate linear regression analysis where the dots represent states. Asterisked variables were significant on multivariate analysis, and significant multivariate coefficients are listed within the panels. On multivariate analysis, state-level dialysis cost demonstrated was the only significant predictor of ROI at 1 y, with a modest effect size of 0.82. However, at 3 y, increases in dialysis cost were associated with large increases in ROI, $\beta = 4.40$. At 5 y, both state-level dialysis costs ($\beta = 4.40$) and median waiting time ($\beta = 3.77$) were both associated with ROI on multivariate analysis and were highly significant. Notably, over time, there was a trend toward lower ROI in states with less transplant center competition, but HHI was not significant in any multivariate model of ROI

There are several limitations of this analysis. Calculations of ROI were based on several assumptions, which were generally based on real world clinical transplant decision-making. The ROI calculations are based on model assumptions for the living donor kidney transplant and dialysis populations, which may not reflect the clinical course or financial savings for an individual patient. The assumptions also do not include variations in costs of care for dialysis-related or transplant-related complications, which could result in cost outliers and potentially affect ROI. An individual's dialysis or transplant costs may vary from another individual's costs, and it is possible that patients who receive living donor transplants may have lower annual dialysis costs on average than those who wait for a deceased donor transplant, which could affect ROI. The magnitude of the ROI calculation was driven by the average cost of dialysis compared to the average cost of transplant, so it is unlikely that any limitations related to ROI calculation assumptions would overshadow the overall effect of the NLDAC program. The ROI calculations also accounted for the fact that 75% of NLDAC donors could not have donated without NLDAC, which may be a biased estimate obtained from NLDAC surveys. However, our sensitivity analysis indicates that positive NLDAC ROI was present even if as few as 10% of potential donors would not have donated without NLDAC (ie, 90% of NLDAC applicants would have donated anyway even if NLDAC was absent). Finally, we did not account for the temporary increase in spending that would be associated with incremental living donor transplants in recipients not yet receiving chronic dialysis therapy and its associated cost. A substantial proportion of living donor kidney transplants are performed just prior to the need for dialysis, so the 1-year ROI might be lower for such patients. Nonetheless, given that pre-emptive transplant recipients would soon need dialysis anyway, the long-term financial benefit of incremental living donor transplants made possible by the NLDAC program would still accrue. Finally, we did not account for post-transplant health care costs, which are known to average much less annually than the costs of dialysis, especially in the living donor transplant context.

This analysis has important policy and health care financing implications. Further expansion of donor financial assistance programs would yield additional cost savings for ESRD payers (primarily CMS), which could be subsidized by federal spending or by other means. Such expansion could include increased budgets for potential donors, relaxed income criteria for eligibility, and reimbursement of other donor out-of-pocket costs such as lost wages.¹⁰ Even if NLDAC funding remains static, the program will continue to yield significant savings and clinical benefits to patients with end-stage organ failure. NLDAC funding expansion will continue to yield the large per-patient financial savings demonstrated here, but would contribute to further savings in aggregate by expanding the availability of living donor transplantation in the USA. It also would have major downstream effects to those remaining on the waiting list—there would be proportional growth in deceased donor kidney transplantation to different patients. The clinical and financial

benefits of program expansion are obvious in this context, which benefits all stakeholders in the kidney transplant process.

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AUTHORS' CONTRIBUTIONS

Robert M. Merion, Amit K. Mathur, Jiawei Xing, David M. Dickinson, Patricia H. Warren, Kimberly A. Gifford, Barry A. Hong, Akinlolu Ojo: participated in research design; Robert M. Merion, Amit K. Mathur, Jiawei Xing, Patricia H. Warren, Akinlolu Ojo, Kimberly A. Gifford, Barry A. Hong: participated in the writing of the manuscript; Robert M. Merion, Amit K. Mathur, Jiawei Xing, Patricia H. Warren, Kimberly A. Gifford, Barry A. Hong, Akinlolu Ojo: participated in the performance of the research; Amit K. Mathur, Jiawei Xing, David M. Dickinson: contributed new reagents or analytic tools; Robert M. Merion, Jiawei Xing, Amit K. Mathur, David M. Dickinson, Akinlolu Ojo: participated in data analysis. Each author contributed important intellectual content during manuscript drafting or revision and accepts accountability for the overall work by ensuring that questions pertaining to the accuracy or integrity of any portion of the work are appropriately investigated and resolved.

CONFLICT OF INTEREST

The authors of this manuscript have no conflicts of interest to disclose.

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SUPPORTING INFORMATION

Additional supporting information may be found online in the Supporting Information section at the end of the article.

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