

Development of the National Living Donor Assistance Center: reducing financial disincentives to living organ donation

Over the years, the transplant community has worked to advance the care of living organ donors; however, barriers remain, including the nonmedical expenses incurred by living donors. A new center, funded by a grant from the Health Resources and Services Administration (HRSA), was established to operate a nationwide system to remove these financial disincentives. The HRSA grant was awarded to an academic institution and the daily operations are managed by a transplant professional society. Expenses are reimbursed prospectively for financially needy living donors. Combining the legislative authority and economic resources of the federal government, the research experience of an academic institution, and the management know-how of a professional society has proven to be successful. To date, the center has received 3918 applications submitted by 199 different transplant centers and receives about 80 applications per month. On average, a donor spends \$2767 for their travel expenses to the transplant center. Of the 3918 applications that have been submitted, 1941 of those applicants (50%) have completed their donor surgery. (*Progress in Transplantation*. 2014;24:76-81)

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On November 8, 2007, the National Living Donor Assistance Center (NLDAC) received its first application to pay for travel and subsistence expenses for a living donor. The application was approved, the surgery was completed and \$2057.62 was spent from the donor's individual NLDAC electronic account. Since that time, more than 3000 applications have been received and nearly \$5 million has been allocated to help living donors with their travel and subsistence expenses. Today, NLDAC has become an integral part of the living organ donation process across the United States by removing financial barriers for living donors, building on years of work developing the program before the first application was ever received. In this article, we describe how the program was authorized,

who provides oversight and guidance, how eligibility guidelines were determined, how the project became operational, and the program's outcomes.

Each year, about 6500 living donor kidney and liver transplants are performed in the United States. The recipients of these living donor organs have higher graft and patient survival rates than do recipients of deceased donor transplants.¹ Many donors are willing to help a family member or friend even though they will most likely have unreimbursed expenses or loss of income. Donation-related expenses may consume more than 1 month's income for 76% of donors.² The direct costs related to travel and accommodations for living donors vary. The expenses often depend on the distance the donor needs to travel from their home to

the transplant center. A review³ of 35 studies from 12 countries revealed travel and/or accommodation costs were incurred by 9% to 99% of living donors. Providing financial support for living donors has been identified as an essential part of donor care in the United States, as well as other countries. In 1 global study,⁴ researchers reported that donor reimbursement programs existed in 21 out of 40 countries.

The US Department of Health and Human Services (HHS) recognized that many persons may want to become living donors for family or acquaintances but lack the necessary resources to cover expenses not covered by insurance. On April 11, 2006, the HHS announced the opportunity to fund a new program to help reduce financial disincentives to living organ donation. This new program, funded by the Division of Transplantation, Healthcare Systems Bureau, Health Resources and Services Administration (HRSA), HHS, would establish and operate a nationwide system to provide reimbursement for travel and subsistence expenses and other nonmedical expenses up to \$2 million yearly with priority to be given to persons who cannot otherwise afford the expenses. On September 14, 2006, after a competitive bidding process, the grant was awarded to the University of Michigan in partnership with the American Society of Transplant Surgeons. The grant was reauthorized in 2010 for an additional 4 years.

Authorizing Legislation

Policymakers, clinicians, and advocacy groups were responsible for establishing NLDAC in 2006 through the Organ Donation Recovery and Improvement Act (ODRIA)⁵ and the National Organ Transplant Act (NOTA).⁶ These 2 legislative acts provide NLDAC's framework.

NOTA, passed in 1984, created the Organ Procurement and Transplantation Network and the Scientific Registry of Transplant Recipients, as well as the Division of Transplantation to administer these activities. It also included criminal prohibition against the exchange of organs for valuable consideration. NOTA defines valuable consideration and explicitly states that it does not include reasonable payments associated with the expenses of travel, housing, and lost wages incurred by the donor of a human organ. In 2007, NOTA was amended to clarify that paired donation is not considered valuable consideration.

The ODRIA, passed in 2004, expanded the authority of NOTA to include founding grant programs and established that the Secretary of HHS may award grants toward the reimbursement of travel and subsistence expenses incurred toward living organ donation. The act describes which expenses would qualify for reimbursement, to whom preference should be given, and the relationship to other payers. ODRIA

states that individuals may not receive compensation from the grant if it is reasonable for these expenses to be paid by a state or federal program, an insurance company, or the recipient of the organ.

Establishing a Framework of Guidance and Oversight

A key component of building the program was gathering input from the public as well as health care experts. Three distinct groups were involved in NLDAC's development and manage its operations: the program team, the advisory group, and the application review committee. The program team oversees the operations of NLDAC and consists of the project director, deputy director, research scientist, HRSA project officer, project manager, project coordinator, project assistant coordinator, and project specialist.

The advisory group is composed of 11 multidisciplinary expert volunteers who meet annually to review program operations and make recommendations as needed. Members of the advisory group have expertise in health care economics, social work, transplant nephrology, transplant surgery, transplant finances, and transplant nursing. One member is a living kidney donor and another is a living liver donor. The advisory group made recommendations on program eligibility later finalized by HRSA.

The application review committee is responsible for reviewing applications each week and approving those that meet the program eligibility guidelines. Members include a transplant social worker recommended by the Society for Transplant Social Workers; a transplant nurse coordinator recommended by NATCO, the Organization for Transplant Professionals; and a transplant recipient recommended by the National Kidney Foundation. These committee members are paid a nominal honorarium to review web-based applications weekly. The NLDAC coordinator and assistant coordinator are also members of the review committee and review applications weekly.

Eligibility Guidelines

Because NLDAC is funded by a federal grant, the program is required to follow the legislative parameters established in ODRIA. ODRIA states that the program must be the payer of last resort and that individuals may not receive compensation from the grant if these expenses can reasonably be paid by a state or federal program, an insurance company, or the recipient of the organ. ODRIA requires means testing of the recipient's household income.

Means testing the recipient's household income to determine donor eligibility was a new concept in live organ donation. Some transplant professionals questioned whether it was legal and/or ethical to means test the recipient's income. Because ODRIA clearly states



Figure Policy development timeline.

the recipient income must be considered in determining eligibility and NOTA allows the recipient to reimburse travel costs, housing expenses, and lost wages for living donors, educating transplant professionals about these public policy requirements was a priority.

For donors participating in kidney paired donation, eligibility criteria are based on the originally intended recipient. For nondirected donors, a recipient must be identified before an application can be filed with NLDAC. Because nondirected donors do not have a recipient identified before their evaluation trip to a transplant center, NLDAC cannot reimburse those expenses. However, after a recipient is identified, an NLDAC application may then be filed.

Throughout the process of developing the guidelines, comments were requested from the public via postings on the *Federal Register*. The advisory group met for the first time in Arlington, Virginia, on February 9, 2007, to develop recommendations. HRSA reviewed the recommended guidelines, made revisions, and published them in the *Federal Register* with an invitation for public comments on April 9, 2007. An income threshold of 300% of the HHS poverty guidelines was established. After the comment period, HRSA published the final eligibility guidelines with a response to the comments on October 5, 2007. The final guidelines established the following criteria for donor reimbursement: travel and other qualifying expenses are incurred toward the intended donation of an organ in good faith, the donor and the recipient are US citizens or lawfully admitted residents whose primary residence is in the United States or its territories, travel originates from the donor's primary residence, the donor and the recipient must certify that they are not participating in valuable consideration of a human organ, and finally the transplant center where the donation occurs certifies its status of good standing with the Organ Procurement and Transplantation Network. The guidelines were amended twice. On June 20, 2008, they were amended to allow donors to make additional trips to the transplant center. On June 19, 2009, the guidelines were amended to allow follow-up visits within 2 years to align them with OPTN policy⁷ (see Figure).

Preference Categories

Because funding is limited and preference is given to persons who would otherwise be unable to afford the expenses of travel to the transplant center, 4 preference categories were established to determine eligibility and an income threshold was set at 300% of the HHS poverty guidelines. The 4 categories are described as follows: category 1, the donor's income and the recipient's income are each 300% or less of the HHS poverty guidelines; category 2, the donor's income is above 300% of the HHS poverty guidelines but can demonstrate financial hardship and the recipient's income is 300% or less of the HHS poverty guidelines; category 3, any living organ donor regardless of income or financial hardship, if the recipient's income is at or below 300% of the HHS poverty guidelines; category 4, any living organ donor regardless of income or financial hardship, if the recipient's income is more than 300% of the HHS poverty guidelines and the recipient is able to demonstrate financial hardship (Table 1).

Financial hardship is demonstrated by calculating annual out-of-pocket allowable expenses and possible lost income. If the expenses equal the income overage, the application may be approved for funding. The allowable expenses include out-of-pocket insurance premiums, medical copayments, medical bills owed, transportation for medical treatment, loss of wages, and financial support for a family member not living in the household. When a waiver for financial hardship is requested by an applicant, HRSA appraises the review committee's recommendation. HRSA is responsible for the final decision to approve or deny a waiver for financial hardship.

Qualifying Expenses

Qualifying expenses are also defined by the eligibility guidelines. The program may reimburse the expenses of travel, lodging, meals and incidental expenses incurred by the donor and/or his/her accompanying person as part of the donor evaluation, hospitalization, and surgical or medical follow-up. The program pays for up to 5 trips, 3 for the donor and 2 for accompanying persons. If the transplant center

Table 1 Descriptions of preference categories

Preference category	Income requirements
1	The donor's income and the recipient's income are each 300% or less of Health and Human Services (HHS) poverty guidelines in effect at the time of the eligibility determination in their respective states of primary residence.
2	Although the donor's income exceeds 300% of the HHS poverty guidelines in effect in the state of primary residence at the time of the eligibility determination, the donor demonstrates financial hardship. The recipient's income is at or below 300% of the HHS poverty guidelines in effect in the state of primary residence at the time of the eligibility determination.
3	Any living organ donor, regardless of income or financial hardship, if the recipient's income is at or below 300% of the HHS poverty guidelines in effect in the recipient's state of primary residence at the time of the eligibility determination.
4	Any living organ donor, regardless of income or financial hardship, if the recipient (with income above 300% of the HHS poverty guidelines in effect in the state of primary residence at the time of the eligibility determination) demonstrates financial hardship.

requests that the donor return to the transplant center, the program may reimburse additional trips. The total reimbursement for the donor and accompanying persons during the donation process is capped at \$6000.

Other eligibility criteria include limiting the number of prospective donors per recipient. The maximum number of donors per recipient for reimbursement is 3 for kidney transplants, 5 for liver transplants, and 6 for lung transplants. For donors and recipients participating in a paired exchange program, eligibility is based on the income of the recipient of the original incompatible pair.

Establishing Operations

While the eligibility guidelines were being finalized, the program's operations were being put in place. The operation component of the program included developing the website and web-based application; hiring staff; setting performance improvement measures; writing contracts with the webhost, bank, and travel agency; developing a marketing plan and educational materials; and writing and implementing policies and procedures for the program.

Website development began as soon as the grant was approved in late 2006. Transplant Informatics Incorporated, a subsidiary of the United Network for Organ Sharing, was selected as the webhost because of the company's understanding of organ transplant policies and protection of health care information. The

NLDAC website serves as a resource for public and professional education and offers application worksheets, brochures, eligibility guidelines, and educational videos. Transplant programs and transplant professionals were required to register with NLDAC before submitting applications. After registration, a password-protected login provides access to the web-based application.

The NLDAC office is located in the national office of the American Society of Transplant Surgeons in Arlington, Virginia. The executive director of the society serves as the NLDAC program manager. The daily operations of NLDAC are managed by the program manager, coordinator, assistant coordinator, and specialist. Contracts were signed with a travel agency to provide assistance with donor travel and with a bank to provide funding to approved applicants by using a controlled value card.

The use of the controlled value card, which works like a credit card, is one of the unique features of NLDAC. Each approved applicant is issued a controlled value card that draws from the donor's individual account. Funding is added or removed electronically by NLDAC staff as needed for travel. Each account has an individual credit limit based on the donor's travel budget, and the account balance declines as funding is used. These electronic accounts allow a high level of control over how the funds are spent by allowing or denying specific merchant codes. Merchant codes not related to travel are excluded, and if a purchase is attempted at an excluded merchant, the transaction is denied. If the merchant does not take a credit card, the program allows each donor up to 25% in cash from the total credit limit established. The account management software provides a record of each donor's expenses. If a donor does not use all the money in the account, the remaining funds are removed and returned to the program.

On October 17, 2007, NLDAC officially launched and began accepting applications. Marketing the program began with launching the website. Because applications are filed by the transplant center on behalf of the living donor, the marketing was directed at transplant center professionals. To start the flow of applications to NLDAC, a series of national conference calls provided training to transplant professionals. A monthly NLDAC electronic newsletter provides program updates, application worksheets, and brochures for patients, to nearly 2000 transplant professionals.

The Application and Approval Process

The NLDAC database demonstrates that 60% of applications are filed by transplant social workers, 20% by registered nurses, 10% by financial coordinators, and 10% by other allied health care professionals. To complete an application, the recipient and

Table 2 Performance measures from November 8, 2007, to August 31, 2013

Performance measure	Expected outcome	Actual outcome
Mean number of applications received monthly	40.0	80
Mean percentage of applications complete when filed	75	96
Days until funding decision is made and applicants contacted	14-21	6.9
Days until donor receives controlled value card after application approved	14	7.7
Mean return rate on donor follow-up survey, %	75	63.6

donor complete an application worksheet and gather income documents to verify their household incomes. Those documents are given to the registered filer, who inputs the data into the web-based application. Completed web-based applications are made available to the application review committee every Monday, and their approval or denial response is due by Thursday of the same week. NLDAC requires 10 business days to review, approve, and fund an application. If an applicant is requesting a waiver, 15 business days are required. An exception is made if a recipient needs a liver transplant urgently. For critically ill liver recipients, applications for their donor may be approved in 1 business day. Approved applicants receive a phone call from an NLDAC team member and are given verbal and written instructions. After the contact information is verified, a controlled value card is ordered. Funds for airfare are made available as soon as an appointment is scheduled. The other funding is made available to the donor 1 week before travel, 1 trip at a time.

Performance Measures

HRSA required performance measures for the program be established early. The performance measures focus on the application submission, timeliness of the approval process, and the donor follow-up survey. The performance measures are (1) the program will receive 40 applications monthly, (2) 75% of all applications will be complete within 48 hours of submission, (3) a funding decision will be made and the applicant will be contacted 14 to 21 days after an application is complete, (4) approved donors will receive a controlled value card within 14 days after an application is approved, and (5) 75% of the donors will return the follow-up survey. To date, all the performance measures have been met except for the return rate of the follow-up survey. Currently, the return rate for the

Table 3 Donor demographic characteristics from November 8, 2007, to August 31, 2013

Characteristic	%
Female	62.7
Male	37.3
Blood relative	61.6
Not a blood relative	19.5
Unrelated	18.9
White	78.9
Black	16.2
American Indian	2.1
Asian	1.7
Native American or Pacific Islander	1.1
White/Hispanic or Latino	17.1

follow-up survey is 70.5% for donors who complete their surgery, 42.3% for potential donors who participate in the program but for whom surgery is ruled out, and 63.6% overall (Table 2).

Program Outcomes

From the first application on November 8, 2007, until August 31, 2013, the program has received a total of 3918 applications and receives on average 80 applications per month from 199 unique transplant centers. Preference category 1 represents 68.7% of the applications, preference category 2 represents 0.7%, preference category 3 represents 15.1%, and preference category 4 represents 15.7%. The application approval rate is 89%.

As noted, the program has received 3918 applications, and when this article was written, 1941 of those applicants (50%) had completed their donor surgery. Kidney donors represented 94.2% of all applications and liver donors made up 5.8%. The program has received 1 application for a living lung donor. The donor demographics for the program reveal: 62.7% female; 37.3% male; 78.9% white, 16.2% black, 1.1% Native Hawaiian or Pacific Islander, 2.1% American Indian, and 1.7% Asian. The donors are identified as Hispanic at a rate of 17.1%. The relationship of the donor to the recipient was as follows: 61.6% were blood relatives, 19.5% were nonblood relatives, and 18.9% were unrelated (Table 3).

The program was established to help low-income donors and recipients. The median household income for the recipient is \$25 842 with a household of 2.7 and the donor median income is \$31 173 with a household of 2.9. Although NLDAC does not reimburse lost wages for donors, the application allows the donor to estimate lost wages while recovering from

Table 4 Program outcomes from November 8, 2007, to August 31, 2013

Outcome	Value
Median income in recipient household, \$	25 842
Mean number of persons in recipient household	2.7
Median income in donor household, \$	31 173
Mean number of persons in donor household	2.9
Donor mean travel expense, ruled out, \$	1077
Donor mean travel expense, surgery complete, \$	2767
Donor mean lost wages, \$	2784

surgery. Lost wages were identified by 1548 applicants (39.0%), and the mean amount of lost income per donor, excluding sick pay, disability, and vacation time, was \$2784.11 (Table 4).

On average, a donor who travels to the transplant center and is later ruled out spends \$1077 and a donor who completes their donation spends \$2767. There is no mileage requirement on how far the donor must live from the transplant center, and some transplant centers use NLDAC to help donors who live nearby with food, gas, and parking. Currently, the program is spending \$131 249 per month on donor travel and has budgeted \$1.8 million for fiscal year 2013.

Conclusion

Living organ donors depend on the transplant community to provide quality care and support. Transplant centers across the nation have embraced the NLDAC, and the number of applications has increased every year. Funding is dependent on the federal grant, and if the numbers of applications continue to increase, the preference categories allow the program to prioritize reimbursement to those donors who would be less likely to afford the direct expense of travel and accommodations.

NLDAC has become an important source of support for many donors. Combining the legislative authority and economic resources of the federal government, the research experience of an academic institution, and the management know-how of a professional society has proven to be a successful combination for NLDAC. Gathering a team of experts to recommend eligibility guidelines and asking the public to comment on those guidelines established a strong foundation for growth. The number of donors who are supported by NLDAC and transplant center participation has grown each year, and NLDAC plans on continued growth in the coming year.

Financial Disclosures

None reported.

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