AJKD
Perspective

Living Donor Kidney Transplantation in the United States—Looking Back, Looking Forward

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There is a desperate need for kidney donors. Twenty-five years ago, we urged more widespread acceptance of unrelated living donors for kidney transplantation. Since then, 2 of us have donated a kidney to an unrelated recipient. In our view, the major challenges for living donor transplantation today are to improve access to this extraordinary gift of life and ensure its safety. Our perspective is that altruism is the motivation for most living kidney donors and the decision to donate represents a shared responsibility among the donor, the donor's physician, and the team of professionals at the transplant center. Thus, sound knowledge of the benefits and risks to donors and recipients is required for informed decisions, and all parties share in the responsibility for the outcomes after living kidney donation. We encourage our colleagues and agencies within the US Department of Health and Human Services to accept the responsibility to do their utmost to provide access to this life-enhancing procedure and systematically evaluate the safety of kidney donation as it evolves to meet the needs of more of our patients.
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INDEX WORDS: Living kidney donor; transplantation; chronic kidney disease; albuminuria; estimated GFR.

Twenty-five years ago, we urged more widespread acceptance of unrelated living donors for kidney transplantation, but also voiced concerns about the obligations of transplant centers as the guardians of access to kidney donation and donor safety.[1,2] Since then, we have each remained active in academic kidney transplant centers, and 2 of us have donated a kidney; one donated to one of our patients 8 years ago, the other donated to a spouse as part of a 3-pair exchange 1 year ago. Biologically unrelated living kidney transplants now account for 14% of all kidney transplants in the United States, and nonspousal donations outnumber spousal donations 2 to 1.[3] The recent growth of regional paired kidney donation programs and the inauguration of a pilot federal program this year are likely to increase further the number of living donor transplants.[4,5] Therefore, we suggest that this is an appropriate time to again call attention to what we consider to be the major challenges that lie ahead for living donor transplantation—improving access to this extraordinary gift of life and ensuring its safety.

Our perspective is guided by 2 main observations. First, altruism—the desire to help another person in need—is the motivation for most kidney donors, whether they are related or unrelated to the recipient. The decision to donate is informed by the knowledge that kidney donation is safe and transplantation provides the recipient with the best opportunity for improved health, survival, and quality of life. Sound knowledge of the benefits and risks to donors and recipients is the underpinning of kidney transplantation from living donors. Second, the decision to donate represents a shared responsibility among the donor, the donor's physician, and the team of professionals at the transplant center. As such, all parties share in the responsibility for the outcomes after living kidney donation. The acknowledgement of shared responsibility is integral to establishing trust with each potential donor and sustaining the current system. This perspective, together with a brief review of the current status of living donor transplantation in the United States, leads us to conclude that transplant professionals and US government agencies that regulate transplantation should redouble their efforts to evaluate the barriers to access and long-term consequences of kidney donation.

NEED FOR LIVING KIDNEY DONORS AND POTENTIAL BARRIERS TO KIDNEY DONATION

There is a desperate need for kidney donors.[6] Life expectancy for kidney transplant recipients far exceeds that for similar patients treated using dialysis.[7] The total number of patients on the active waiting list far exceeds the number of deceased donor organs recovered each year, and waiting times surpass 3 years nationally (Fig 1).[3] These trends are likely to continue because there is an increasing prevalence of both kidney failure and earlier stages of chronic

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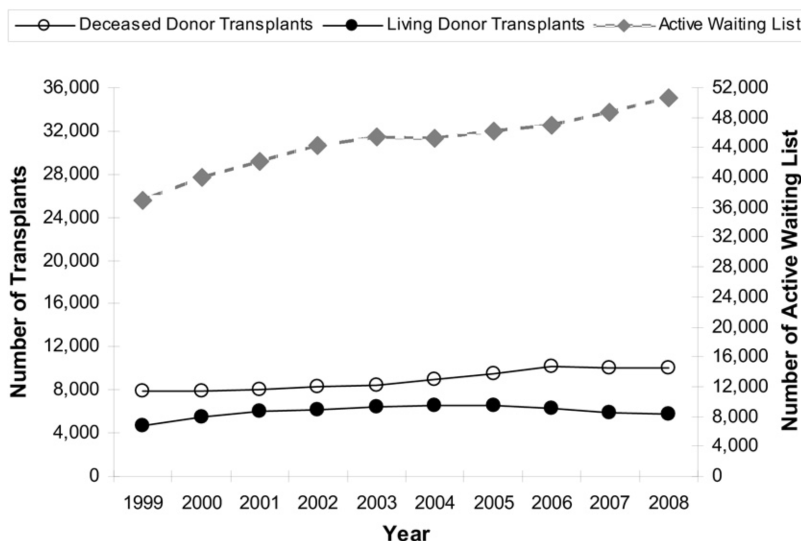

Figure 1. Number of patients on the waiting list, number of transplants from deceased and living donors performed by year. Data source: Organ Procurement and Transplantation Network and Scientific Registry of Transplant Recipients.[3]

kidney disease.[8] Hypertension and diabetes, the 2 most common causes of chronic kidney disease, are becoming more common in the general population. Characteristics of patients developing kidney failure are changing. An increasing proportion are elderly, of racial and ethnic minority background, of lower socioeconomic status, and have diabetes, hypertension, or obesity.[7,9]

Characteristics of living donors also are changing. A higher proportion of donors are now older, overweight, or members of racial and ethnic minorities.[10] Nonetheless, on a national level, there are marked differences in characteristics of patients awaiting transplant and donors (Table 1).[3] Although the difference in age is expected, the persistent differences in sex and race-ethnicity may reflect barriers to access to donation, particularly socioeconomic and cultural barriers. For example, living donation is less common in those with less education, lower income, inadequate medical insurance coverage, and less trust in physicians.[11-13] Preliminary evidence suggests that donation rates have decreased sharply in those with the lowest incomes during the recent economic downturn.[14] There are wide geographic and programmatic variations in living donation in the United States, spanning both related and unrelated donation, the causes of which are not fully understood. Some programs do not accept kidney donors who do not have their own health insurance. Other factors, including professional education, program size and staffing, and availability of laparoscopic nephrectomy and other resources, likely have a role.

SAFETY OF LIVING KIDNEY DONATION

The criteria for kidney donation are designed to select medically and psychologically healthy donors with minimal short- and long-term risk for complications of the procedure.[15] Extensive and detailed guidelines have been developed for the evaluation of living donors in general and specifically for unrelated donors.[16,17] Some programs now accept older donors and those with well-controlled hypertension, obesity, or other medical conditions that are judged to be of low short- or long-term risk, although there is substantial variation among programs.[18]

The short-term consequences of kidney donation are well known. Mortality within 90 days is 0.031% and has not changed in the past 15 years.[10] Complica-

Table 1. Characteristics of Waiting List Patients and Living Kidney Donors

	Patients on the Active Waiting List in 2008	Living Kidney Donors 1999-2008
No.	50,624	64,225
Age category		
<18 y	0.9	<0.01
18-34 y	11.1	33.3
35-49 y	29.0	46.0
50-64 y	42.3	19.7
>65 y	16.7	0.8
Sex		
M	58.7	41.9
F	41.3	58.1
Race-ethnicity		
White	38.0	70.2
African American	33.8	12.8
Hispanic/Latino	18.4	12.5
Asian	8.4	3.4
Other/multirace	1.4	0.9

Note: Categorical variables given as percentages. Waiting list comprises patients waiting for a deceased donor kidney.

Data source: Organ Procurement and Transplantation Network and Scientific Registry of Transplant Recipients.[3]

tions requiring surgical or radiologic intervention under local or general anesthesia occurred in <3% in 2 large series.[19,20] These rates are much less than the levels of risk that are regarded as acceptable for other elective surgical procedures. After kidney donation, measured glomerular filtration rate (GFR) decreases to ~70% of predonation levels, and urinary albumin excretion is minimally increased, implying glomerular hyperfiltration and some increase in glomerular permeability to albumin in the remaining kidney.[21] These measures are not accompanied by complications or symptoms of chronic kidney disease.

Long-term consequences of kidney donation are not as well known. Survival appears better than for control populations matched for age and the absence of comorbid conditions that are regarded as contraindications to donation.[10] These data are consistent with the excellent long-term outcomes of young adults who underwent nephrectomy for trauma.[22] However, there remains some uncertainty because kidney donors typically are screened more carefully for comorbid conditions than controls in these studies. Blood pressure in donors appears to be higher than in controls, and there is a small increased risk for the development of hypertension.[23] A study of 255 donors at a mean of 12.2 years after donation at the University of Minnesota showed a mean measured GFR of 72 mL/min/1.73 m^2 and geometric mean albumin-creatinine ratio (ACR) of 4.7 mg/g.[24] Values for GFR were lower and values for albuminuria were higher with older age and longer time since transplant. In our opinion, these data are adequate to provide reassurance of the long-term safety of kidney transplantation from living kidney donors.

However, there remain several sources of concern about the long-term risks to kidney donors. Glomerular hyperfiltration and increased permeability to albumin are associated with progressive kidney disease in experimental animals with extensive reduction in renal mass.[25] Approximately 12% and 4% of donors have estimated GFRs or urine ACRs that meet the definition for chronic kidney disease (GFR <60 mL/min/1.73 m^2 or urine ACR >30 mg/g).[26] It is now widely accepted that these kidney measures are associated with an increased risk for future adverse events in the general population, including all-cause and cardiovascular mortality and kidney disease, even after adjustment for known risk factors.[27] Nephrectomy for renal cell cancer in older adults is associated with increased risk for estimated GFR <60 mL/min/1.73 m^2 and for all-cause and cardiovascular mortality compared with partial nephrectomy.[28] However, these associations do not prove cause and effect because there may be residual confounding of risk factors for kidney and cardiovascular disease with these kidney measures in the general population and in patients with renal cell cancer. Furthermore, it would not be appropriate to generalize observations from these study populations to the highly selected population of kidney donors, and there is active debate about the applicability of these thresholds for the definition of chronic kidney disease to kidney donors.[29-31] However, there have been no large studies of cardiovascular and kidney outcomes in kidney donors; donors are not free from risk from conditions such as obesity, hypertension, and diabetes that increase the risk for subsequent cardiovascular and kidney disease, and donors are living longer, thereby increasing their risk to acquire these conditions.

Recent reports have called attention to the small number of donors that have developed kidney failure.[32] Age at onset of kidney failure ranged from 25-70 years, and the interval between donation and kidney failure ranged from 2-32 years. Blacks, males, and younger donors were disproportionately represented.[33] These data are consistent with another recent report that blacks and Hispanics have a higher risk for developing hypertension, diabetes, and chronic kidney disease after kidney donation.[34] However, these groups also have a higher risk for kidney disease in the general population, and there are not sufficient data to estimate the relative risk from kidney donation per se.

On balance, it seems most appropriate to acknowledge some uncertainty about long-term risks for adverse outcomes of kidney donation, particularly in higher risk populations. In our view, the uncertainty may be large enough to cause discomfort in counseling some potential donors and in medical decision making after donation. This is especially important as the criteria for living kidney donation are evolving.

EVALUATION OF RISK

Evaluation of potential kidney donors is guided by the need to balance the ethical principles of preserving the autonomy of donors and protecting them from risk. The importance of both principles is heightened in dealing with higher risk populations. Ideally, there should be explicit thresholds for short- and long-term risks for kidney donation above which the transplant team can reasonably decline to perform the donor nephrectomy and below which the donor is free to make his or her own decision.[35] Donor short- and long-term risks would be computed as the product of absolute risk due to demographic and clinical factors (baseline risk) times the relative risk due to kidney donation. Comparison of donor risks to these explicit risk thresholds would enable determination of eligibility and facilitate medical decision making after donation. However, to our knowledge, there are no univer-

Table 2. Roles and Responsibilities for Donor Identification, Evaluation, and Follow-up

Role	Responsibility	Explanation
Identification and referral of transplant candidates	Dialysis physicians and dialysis units	CMS requires physician assessment of transplant candidacy as part of annual long-term care plan. The patient record must show evidence that the patient was informed about transplantation as an option, living and deceased kidney donation, area transplant center(s), and each transplant facility's selection criteria.
Identification of donor candidates	Transplant center	Transplant centers generally ask transplant candidates to refer donor candidates to the center.
Evaluation of donor candidates	Transplant center	OPTN establishes medical criteria for acceptability.
Payment for medical expenses related to donor evaluation	Recipient health insurance carrier (Medicare, Medicaid, and private insurance)	Common practice, but variability in implementation among carriers.
Reimbursement for nonmedical expenses related to donation	Recipient, family, friends, and voluntary programs	Permitted by National Organ Transplant Act and Declaration of Istanbul.[38] For example, the American Society of Transplant Surgeons National Living Donor Assistance Center provides for travel and lodging expenses for donors and companions, but the program is inadequately funded to reimburse all donors in need, and strict "means-based" criteria are used.[39]
Postdonation medical care	Donor physician and donor health insurance carrier	Transplant programs may take financial responsibility for short-term complications. One survey shows that ≥18% of kidney donors in the United States have no health insurance, with wide variation across regions and transplant centers.[40]
Postdonation health surveillance	Transplant center	OPTN requires reporting of limited data at 1 and 2 y, but there is no provision for payment for medical examinations or laboratory tests to acquire these data. European guidelines recommend periodic follow-up.[41]
Postdonation kidney failure	Donor physician and health insurance carrier (Medicare eligibility similar to other patients with kidney failure)	OPTN assigns priority for allocation of deceased donor kidneys to former living kidney donors.

Abbreviations: CMS, Centers for Medicare & Medicaid Services; OPTN, Organ Procurement and Transplantation Network.

sally accepted risk thresholds and there is inadequate knowledge of baseline and relative risks by age, sex, and race-ethnicity. Transplant centers vary in the manner in which they state risk thresholds and interpretation of donor baseline and relative risks. Overall, this leads to some uncertainty in decision making, which likely is reflected by variation among transplant centers in acceptance of living kidney donors with medical conditions.

Uncertainty in the decision-making process potentially compromises both donor autonomy and protection, thereby threatening the present system of living kidney donation. In our opinion, the short- and long-term risks to most potential donors likely are much less than the threshold to allow them to make their own decisions. Furthermore, we suspect that for many potential donors, including the 2 of us who have donated, the perceived risks are much less than the level that would deter them from the decision to help someone in need. However, for others, more accurate information, especially about long-term risk, may be vital to decision making. Uncertainty about long-term risks may be most relevant for younger donors and members of racial and ethnic minorities that have a higher lifetime risk for developing kidney and cardiovascular disease.[36]

OBLIGATIONS AND EXPECTATIONS

Since the beginning of living donor kidney transplantation, transplant centers have accepted the responsibility for evaluation of potential recipients and living donors.[37] In the United States, the National Organ Transplant Act of 1984 created an Organ Procurement and Transplant Network (OPTN) under the auspices of the Department of Health and Human Services (DHHS) to oversee procurement and allocation of deceased donor organs by transplant centers. Since 2002, the OPTN has overseen living kidney donation and currently has a living donor committee to make policy recommendations for living donor care.

The system that has evolved is complex and lacks systems to ensure access to living donor transplanta-

tion and surveillance for long-term outcomes after kidney donation (Table 2).

What is the role of transplant professionals, transplant centers, and the DHHS in improving access to living donor transplantation and maintaining and evaluating its safety? We believe it is reasonable to expect that the DHHS should strive to improve access to safe living donation and that transplant centers should participate actively. Improved access could translate to increasing transplantation rates, improving outcomes of transplantation, and reducing the burden of kidney failure. Improving access will require better understanding of the barriers to the procedure, particularly for minority populations and the economically disadvantaged. The "collaborative" method, conceived by the Institute for Healthcare Improvement, was used successfully to improve rates of deceased donation and might provide a useful framework to enhance access and the quality of care for both recipients and their potential living donors.[42] We await the report of the conference entitled "Living Kidney Donor Follow-up: State-of-the-Art and Future Directions" held in Crystal City, MD, in September 2010 with participants from the OPTN, National Institutes of Health, voluntary health organizations, an insurance company, and transplant centers from around the world.

We believe it is reasonable to expect that transplant professionals should be the most knowledgeable about long-term risks of kidney donation and that donors should be entitled to referral back to the transplant center for further evaluation in the event of complications thought to be related to kidney donation. Although not systematically studied, we would regard the availability of the transplant center to assist in the care of donors after transplantation as an important element contributing to trust in the current system of kidney donation. Likewise, it is reasonable to expect that the DHHS should mandate some form of long-term surveillance after kidney donation and transplant centers should participate in these efforts. We would anticipate that better information would serve the interests of living donor transplantation by enabling more informed counseling of potential kidney donors and better medical care after transplantation. Improving our understanding of long-term risk will require systematic surveillance after donation through either registries or dedicated research programs, as exist in other countries.[19,43]

CONCLUSIONS

It is a privilege to counsel potential kidney donors and recipients and see first hand the benefits that accrue from the gift of life. With this privilege comes the responsibility to continuously improve access to transplantation for others and our knowledge of the risks and benefits of donation. It is an even greater privilege to have donated a kidney and to have benefitted directly from our profession's dedication to living kidney donation. We encourage our colleagues and agencies within the DHHS to accept the responsibility to do their utmost to provide access to this life-enhancing procedure and systematically evaluate the safety of kidney donation as it evolves to meet the needs of more of our patients.

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