

The Decline in Living Kidney Donation in the United States: Random Variation or Cause for Concern?

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The annual number of living kidney donors in the United States peaked at 6647 in 2004. The preceding decade saw a 120% increase in living kidney donation. However, since 2004, living kidney donation has declined in all but 1 year, resulting in a 13% decline in the annual number of living kidney donors from 2004 to 2011. The proportional decline in living kidney donation has been more pronounced among men, blacks, younger adults, siblings, and parents. In this article, we explore several possible explanations for the decline in living kidney donation, including an increase in medical unsuitability, an aging transplant patient population, financial disincentives, public policies, and shifting practice patterns, among others. We conclude that the decline in living donation is not merely reflective of random variation but one that warrants action by the transplant centers, the broader transplant community, and the state and national governments.

Keywords: Living donation, Live-donor kidney transplantation.

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Live-donor kidney transplantation (LDKT) accounts for one third of kidney transplants performed in the United States and continues to offer superior outcomes compared with maintenance dialysis and deceased-donor kidney transplantation for individuals with end-stage kidney disease (1). Figure 1 shows a remarkable 265% increase in the annual number of living donors from 1988 to 2004. In each year during this time period, there was an increase in living donation relative to the previous year. This increase in living donation may be attributed to several factors, including advances in histocompatibility testing, new laparoscopic surgical techniques, findings of comparable graft survival outcomes with genetically related and unrelated living donors, and greater public awareness about the need for organ donors.

However, since the peak of 6647 donors in 2004, the annual number of living donors has declined from the previous year in all but 1 year (2009) despite the emergence of novel programs to expand kidney donation (2–8). This observed trend differs from recent increases in living donation seen in some regions of the world (e.g., United Kingdom, Japan, The Netherlands, Mexico, and Australia) (9). This recent living donation trend in the United States has not received the scrutiny one might expect in light of its implications for transplant candidates. In this article, we examine the recent decline in living donation, including whether it is specific to certain subgroups or populations, factors that might explain it, and what the transplant community should do, if anything, to attenuate it. Our intent is to stimulate further discussion and scientific inquiry into living donation trends and patterns in the United States.

IS THE DECLINE IN LIVING DONATION SPECIFIC TO PARTICULAR SUBGROUPS OR POPULATIONS?

We extracted data from the Organ Procurement and Transplantation Network (OPTN) Web site to examine trends in living donation within subgroups (1). To facilitate our examination of pattern shifts before and after the peak number of living donors observed in 2004, we divided living donation into two eras reflecting identical time periods: Era 1 (1998–2004) and Era 2 (2005–2011). The proportions of living donors for each category in the two eras were compared using *t* tests for proportions.

Donor Gender

Women represent 57% to 62% of all living donors in each of the last 15 years (Fig. 2). There was a decline in male donors as a proportion of total donors from 41.9% in Era 1

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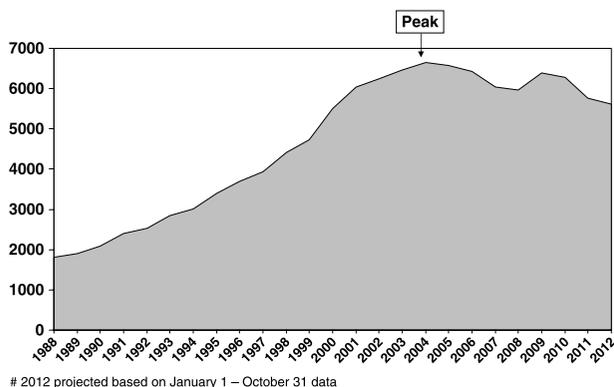


FIGURE 1. Number of living kidney donors, United States, 1988–2012.

to 39.8% in Era 2 ($P=0.006$). The number of male donors peaked in Era 1 (2004) and declined consistently throughout Era 2. In contrast, the three highest annual totals for female donors occurred during Era 2 (2005, 2009, and 2010).

Donor Race/Ethnicity

Non-Hispanic whites represent the majority (70%) of living donors over the last 15 years. Living donation among non-Hispanic whites and blacks peaked in Era 1 (both in 2004). The number of non-Hispanic white ($n=4045$) and black ($n=680$) donors in 2011 are the lowest annual totals for both races in more than a decade. Black donors as a proportion of total donors dropped significantly from 13.4% in Era 1 to 12.2% in Era 2 ($P=0.002$). In contrast, the annual number of both Hispanic and Asian living donors has increased over time, and there was a significant increase in the proportion of total donors from Era 1 to Era 2 for Hispanics and Asians (11.9%–13.6%, $P<0.001$ and 2.9%–3.4%, $P=0.010$, respectively).

Donor Age

There has been a steady decline in the annual number of living donors less than 50 years old since 2004 (Fig. 3). Living donation among adults aged 18 to 34 years and 35 to 49 years peaked in Era 1 (2004) and Era 2 (2005), respectively,

and the number of 2011 donors for both age groups was the lowest in 12 years. Living donors in the 18 to 34 and 35 to 49 age groups as a proportion of total donors dropped significantly from Era 1 to Era 2 (33.5%–30.6%, $P<0.001$ and 46.9%–44.0%, $P=0.002$, respectively). In contrast, the number of annual living donors aged 50 to 64 years increased steadily since 1998. Their proportion of total donors increased from 18.6% in Era 1 to 23.9% in Era 2 ($P<0.001$). Compared with younger donors, the number of annual donors aged 50 to 64 and more than 65 years peaked only more recently in Era 2 (both in 2010).

Donor Relation

Sibling donors, historically the most common type, peaked in Era 1 (2001) and have declined substantially since then. For the first time, in 2010, another type of living donor (unrelated nonspouses) exceeded the annual number of sibling donors. Parent donors, excluding pediatric transplant recipients, also peaked in Era 1 (2001) and have decreased over time, although not as precipitously as sibling donors. The number of sibling ($n=1185$) and parent ($n=323$) donors in 2011 reflects the lowest annual totals for both groups in more than two decades. Both siblings and parents as a proportion of total donors dropped significantly from Era 1 to Era 2 (33.1%–24.1%, $P<0.001$ and 13.9%–9.4%, $P=0.001$, respectively). Both unrelated nonspouse and child donors increased sharply during Era 1, peaked early in Era 2 (2006 and 2005, respectively), and declined in recent years.

Region

All 11 organ procurement regions in the United States experienced an increase in the annual number of living kidney donors from 1998 to 2004 (1). However, the annual number of living donors peaked in Era 1 (Regions 1, 2, 5, and 6) or early in Era 2 (Regions 3, 7, 10, and 11) in the majority of regions. In contrast, more recent peaks (2009 and 2010) in annual living donors have been observed in Region 4 (Oklahoma and Texas), Region 8 (Colorado, Iowa, Kansas, Missouri, Nebraska, and Wyoming), and Region 9 (New York and Western Vermont); indeed, these regions have seen an increase in living donation during Era 2.

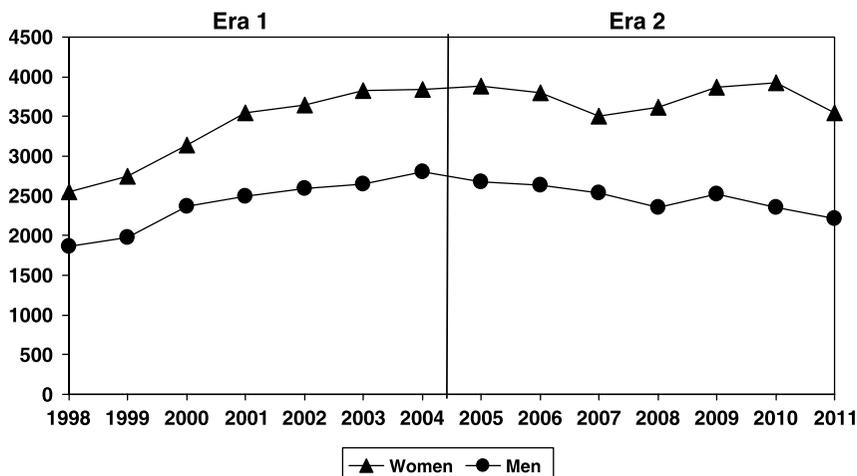


FIGURE 2. Number of living kidney donors by gender and era, United States, 1998–2011.

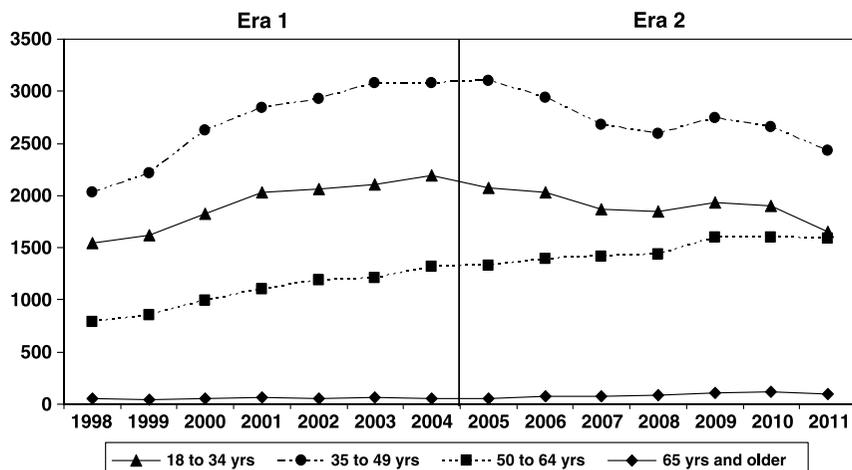


FIGURE 3. Number of living kidney donors by age group, United States, 1998–2011.

Overall, although the annual number of living donors has declined since the peak in 2004, the decline appears more pronounced and sustained among men, blacks, younger adults, siblings, and parents. All of these subgroups reached an annual peak in Era 1 and have been on a persistent decline in Era 2, and their respective 2011 totals were the lowest observed in a decade or more.

WHAT ARE POSSIBLE HYPOTHESES TO EXPLAIN THE DECLINE IN LIVING KIDNEY DONATION?

Change in Deceased-Donor Allocation

In October 2005, the United Network for Organ Sharing implemented a new policy that prioritized the allocation of kidneys from deceased donors less than 35 years old to pediatric candidates less than 18 years old (10). A commonly heard refrain within the transplant community is that the decline in living donation is attributable to this allocation change. The central hypothesis is that preferential access to young deceased-donor kidneys results in substantially shorter waiting time and, consequently, lower LDKT rates. There is some empirical support for this supposition. Agarwal et al. (11) found that the mean waiting time for pediatric patients who received a deceased-donor kidney declined significantly from pre- to post-policy implementation, as did the mean number of LDKTs to pediatric recipients.

However, there are factors that argue against attributing the decline in living donation solely to this allocation policy change. For instance, if the policy change caused the decline in total number of living donors, there would be a decrease in the number of living donors for pediatric candidates and for the total candidate population but not for adult candidates. Instead, we observe that the number of living donors for adult candidates has declined in all but 1 year after policy implementation and there were 11% fewer living donors for adult candidates in 2011 ($n=5468$) compared with 2005 ($n=6148$). Moreover, although there is good evidence that the policy change led to a reduction in LDKT rates for pediatric candidates (11), living donation for pediatric patients had already peaked in 2002 and was in decline before the policy change

in 2005. We conclude, therefore, that the decline in the total number of living donors is partially, but not entirely, due to the allocation policy change in 2005.

Increased Emphasis on Performance Oversight

The Scientific Registry of Transplant Recipients has published outcomes for transplant centers in the United States for over a decade (12). These data contain information on center volume, donor and recipient characteristics, as well as risk-adjusted posttransplantation graft and patient survival. In 2007 (Era 2), the Center for Medicare and Medicaid Services published the Conditions of Participation, which explicitly aligns transplant center outcomes with potential loss of public funding using very similar outcomes as the Scientific Registry of Transplant Recipients (13). One concern of increased regulatory oversight is a suppression of innovation, a decline in the use of novel therapies, and an increase in more conservative policies and practices due to the potential impact on center performance reports (14, 15). Schold et al. (16) recently found that transplant programs receiving a low performance evaluation between 2007 and 2010 had an average reduction of 22 transplants over the study period compared with an average increase of 8 transplants among centers that did not receive a low performance evaluation ($P=0.001$). This difference was significant across donor types, including an average net decrease of 15 LDKTs among centers with a low performance evaluation compared with an average decrease of only 3 LDKTs among centers without a low performance evaluation.

Largely in response to widely publicized deaths of living liver and kidney donors, the Secretary of Health and Human Services directed the OPTN in 2006 (Era 2) to develop policies regarding living organ donors and organ donor recipients and stipulated that program noncompliance with these policies would result in consequences similar to those for noncompliance with OPTN deceased-donor transplantation. The OPTN subsequently developed policy regarding the medical and psychosocial evaluation of potential living donors, the informed consent process, the inclusion of independent living-donor advocates in the evaluation process, and minimum requirements for the submission of

living-donor follow-up data (OPTN Policy 12.0, Living Donation, February 1, 2013).

An important question is whether the increased regulatory oversight and scrutiny of center outcomes will have an appreciable impact on growth of transplantation including living donation. Centers may have more reluctance to select “marginal” candidates or adults for living donation due to the potential impact on center report cards. Also, if centers with performance concerns or insufficient resources to meet new OPTN policy requirements are more reluctant to sustain or expand their LDKT programs, this may contribute to a decline in living donation. Finally, the degree to which increased media attention of living-donor deaths and increased regulatory oversight in Era 2 impacted the willingness of the general public to pursue living kidney donation is unknown, but these factors should be considered when evaluating contributors to the decline in living donation.

Changes in Donor Selection Criteria

In the United States, the expansion of living-donor eligibility criteria is well documented (17–19). This includes not only expanding the types of donors who are acceptable candidates (e.g., unrelated, anonymous nondirected, older donors) but also the medical and psychosocial eligibility criteria. Many more programs have shifted practices and are now willing to consider donors with well-controlled hypertension, mild obesity, and stable psychiatric disorders. It is likely that the increase in living donation observed in Era 1 is attributable, in part, to these shifting donor eligibility criteria.

Although programs may be more willing to evaluate a wider range of potential donors, there may be some retraction in other aspects of the donor evaluation (e.g., moderate obesity). Also, some programs now apply different eligibility criteria across different groups of donor candidates (e.g., race and obesity) based on outcomes published mostly in Era 2 (20–24). For example, young blacks with risk factors for metabolic syndrome may be excluded due to studies demonstrating higher rates of chronic kidney disease (CKD) in this population compared with whites (20, 25). Finally, the availability and evolution of radiologic and histocompatibility

techniques have led to more refined evaluation of the renovascular anatomy and immunocompatibility. For example, increased measurement of donor-specific antibodies may rule out some donor candidates. Although more detailed assessment and testing is warranted in light of expanding eligibility criteria, widespread adoption of more refined testing may be contributing to a higher incidence of donor exclusion in the last decade. It could also be argued that advancements in immunologic and histocompatibility screening have led to the notable growth of kidney exchange and desensitization protocols that have enabled adults—previously considered ineligible—to become living donors (26–28). Although the total number of donors participating in kidney exchanges surged from 65 in Era 1 to 1593 in Era 2, it is too early to determine whether growth in these types of programs can offset the observed decline in living donation rates.

A Changing Transplant Population

Increasingly, older adults comprise the majority of new additions to the kidney transplant waiting list (1, 29, 30). Adults 50 years and older comprised 45% (8437/18,942) of all adults listed for kidney transplantation in 1998, but this representation increased dramatically to 60% (19,540/32,650) in 2011 (Fig. 4). Of particular note is the increase in adults 65 years or older on the waiting list, from 8% (1574/18,942) in 1998 to 17% (5431/32,650) in 2011. One possible implication of the increasingly older transplant population is a correspondingly smaller network of potential living donors for these patients. As adults age, their peripheral social networks contract due to employment loss, retirement, and more restrictions on leisure activities (31). CKD, dialysis treatment, and quality-of-life limitations may further increase social isolation, which may reduce the transplant candidate’s overall pool of potential donors. Moreover, although older living donors may yield favorable transplant outcomes (32, 33), the risk of medical exclusion likely increases with age. Siblings of older transplant candidates increasingly become ineligible for donation due to declining kidney function and comorbidities, and parents are almost always excluded from donation by these factors. The decline in mean household size in the United States during the

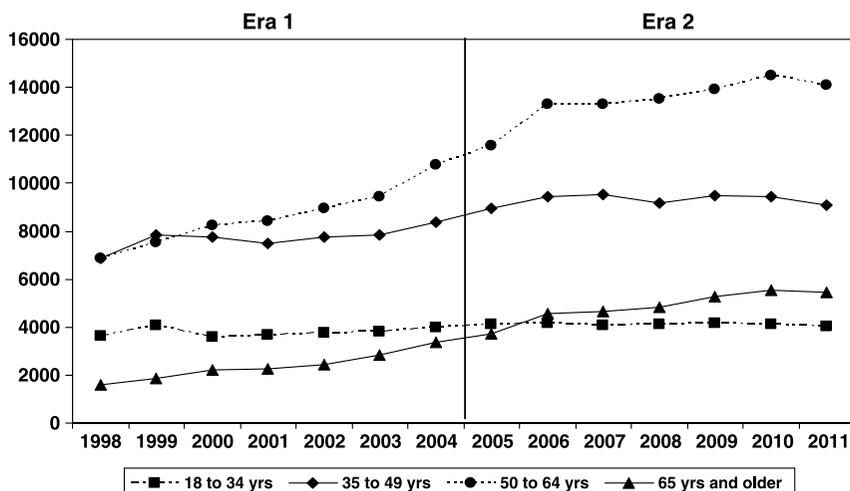


FIGURE 4. Number of adults added to the kidney transplant waiting list by age group, United States, 1998–2011.

last 50 years (3.47 in 1950 to 2.63 in 2009) may also be contributing to the notable retraction in the number of sibling donors. Overall, older transplant candidates simply may not have as many potential donors as younger transplant candidates, which may explain the lower LDKT rate in older adults. In 2011, 50% of transplant recipients 18 to 34 years old received a LDKT compared with only 30% and 26% of recipients 50 to 64 years old and 65 years or older, respectively (1).

Transplant Waiting Time

Shorter waiting times for deceased-donor kidney transplantation might impact center practices (e.g., more stringent donor selection criteria, less likely to implement new programs to increase LDKT rates) as well as the willingness of patients and family members to consider living donation (34). Indeed, there is some evidence that LDKT rates are lower in centers with shorter transplant waiting times (35, 36). However, these studies are based largely on data from Era 1. In light of median waiting times exceeding 5 years in some regions, it cannot yet be determined whether the relationship between waiting time and LDKT rates has been maintained throughout Era 2.

Health Status of the General Population

Obesity, pre-diabetes, diabetes, and hypertension are alarmingly prevalent in the United States (37–40). These health conditions contribute to the incidence of CKD and may also account for a smaller pool of potential living donors, particularly in subgroups with a higher incidence of these risk factors (e.g., Blacks and older adults). Diabetes is an absolute contraindication to living donation, whereas obesity and hypertension are strong relative contraindications in many instances. The percentage of adults with diabetes in the United States increased from 6.3% in Era 1 to 8.1% in Era 2 (41). Similarly, the percentage of obese adults (body mass index >30) increased from 22.7% in Era 1 to 27.4% in Era 2 (42). Collectively, these risk factors are the most common medical reasons for exclusion from living donation, particularly among minorities (43–45).

Financial Disincentives in an Economic Crisis

The economic downturn in the United States is well documented (46). Since 2007, unemployment claims have risen, median household income has declined, and housing foreclosures have increased (46). These economic pressures on individuals and families may have negatively impacted willingness to pursue living donation, especially among those with low or moderate incomes and concerns about employment security. Indeed, Gill et al. (47) showed that the decline in living donation in the United States is most pronounced among adults with lower household income, particularly among blacks.

The indirect and direct costs associated with living donation have not been systematically captured. However, typical costs include those for travel, lodging, meals, childcare, and other service related costs while the donor is recovering (47). Lost wages are common for living donors, even for those with short-term disability or limited medical leave benefits. Out-of-pocket expenses are reported to range from \$0 to \$20,000, with an average of approximately \$5000 when all direct and indirect costs are considered (48–50). In times of economic uncertainty, these costs may be a deterrent to

living donation for otherwise willing potential donors. There may be heightened concerns about employment security or stability during a recession and less willingness to absorb lost wages, which is greater than 1 month's household income for the majority of living donors in the United States (51). Although the U.S. Department of Health and Human Services provides some financial assistance for low-income donors (i.e., National Living Donor Assistance Center), these reimbursements are limited largely to travel and lodging. Reimbursements for lost wages are not permitted as part of this program. Recipients or family members who otherwise might have helped the living donor meet their financial obligations during recovery may be limited by the same financial hardships as the donor. Most transplant recipients have similar incomes to their living donors and therefore may not be able to compensate donors for out-of-pocket expenses (51). Overall, adults may be less willing to assume the financial and occupational risks of living donation during an economic downturn than in more prosperous times, and this may be contributing to the observed decline in living donation in the United States.

WHAT CAN BE DONE TO ATTENUATE THE DECLINE IN LIVING KIDNEY DONATION?

We propose a multilayered approach to attenuate the decline in living kidney donation, one that engages key stakeholders—the transplant centers, the broader transplant community, and the state and national governments. Transplant centers could examine trends in their LDKT rate since 2004 and use existing quality improvement processes to identify, implement, and evaluate strategies to address any downward pressures on LDKT. For instance, some centers have successfully employed patient navigators (6), home-based education (5), dialysis center-based interventions (8), and enhanced educational processes in the transplant center (7, 52, 53) to increase LDKT willingness and rates. These quality improvement initiatives and findings could then be disseminated to the broader transplant community for further evaluation and replication. The broader transplant community, using existing organizational structures (e.g., United Network for Organ Sharing Living Donor Committee and American Society of Transplantation's Living Donor Community of Practice) could identify and disseminate “best practices” for removing barriers to living donation and LDKT as well as develop policies to reduce financial disincentives to living donation. At the level of state and national governments, legislation could be developed to expand tax reduction incentives for living donors and prohibit discrimination against living donors by insurers. Together, the transplant community and government agencies could modify existing legislation and increase funding to allow existing financial assistance programs to reimburse living donors for lost wages. Additionally, transplant regulations and performance report cards must be carefully evaluated for their potential adverse impact on LDKT and living donation accessibility.

The decline in living donation over the last several years is indisputable. It is tempting to attribute this decline to random variation and to assume the number of living donors will return to levels observed in 2004. However, despite novel programs to help patients find suitable living

donors, national financial programs and state tax incentives for living donors, and heightened general public awareness of living kidney donation, there is considerable downward pressure on living donation rates. Furthermore, the recent decline in living donation appears most prominent among men, blacks, and younger and lower income adults, which may further exacerbate existing LDKT disparities (54–59). We believe that this persistent downturn in living donation should be cause for action within the transplant community, as it potentially leads to longer waiting times for transplantation, greater dialysis exposure, higher death rates on the waiting list, lower graft and patient survival for recipients, and higher overall healthcare costs for the care of patients with end-stage renal disease. Programmatic, scientific, policy, and legislative efforts to identify and remove barriers to living donation are needed to ensure that LDKT remains a viable option for patients with CKD.

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