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Living Donor Practices in the United States

Didier A. Mandelbrot, MD¹ and Martha Pavlakis, MD¹

¹The Transplant Institute Beth Israel Deaconess Medical Center 110 Francis Street, 7th floor
Boston, MA 02215 617-632-9700 617-632-9804

Abstract

Living donation is a common procedure in the United States. Substantial variation exists among transplant centers in their protocols and exclusion criteria for potential living donors. In the absence of clinical trial data to guide decisions about exclusion criteria, knowledge of current practices is an important first step in guiding the formulation of donor protocols as well as future studies. Certain trends in live donation practices have become apparent from surveys of transplant programs over the past few decades. Over the past 25 years, opposition in the US to living unrelated donation has gone from strong to essentially nonexistent. With respect to donor age, programs have become less strict regarding upper age limits, but stricter regarding younger donor candidates. Protocols regarding kidney function, blood pressure and diabetes screening also continue to evolve. Although donor follow up is mandated by the OPTN for two years after donation, a majority of donors are lost to follow up by one year. The most commonly cited barriers to donor follow up include donor inconvenience, cost issues including reimbursement to care providers, as well as direct and indirect costs to donors. Here, we review the current knowledge about living donor practices in the U.S.

Keywords

Living Donors; Kidney Transplantation; Donor Screening; Donor Exclusion; Kidney Function Tests

Introduction

The use of living donors for kidney transplantation in the United States is now common, having increased more than three-fold over the past 20 years (figure 1). A number of factors have driven this increase. From the transplant recipients' perspective, the substantial benefits of receiving a kidney from a living donor, as opposed to a deceased donor, have been well documented (1). In addition, technical improvements such as laparoscopic nephrectomy have reduced the morbidity of donation and increased willingness to donate a kidney (2). Finally, recent studies have confirmed the relatively low surgical risk of kidney donation (3), and multiple studies have demonstrated the long-term medical safety of donation by young, healthy, caucasian individuals (4–8). However, substantial variation exists between different transplant centers in their choice of protocols and exclusion criteria for potential living

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Corresponding author dmandelb@bidmc.harvard.edu.

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donors. This variation is partly due to the limited number of studies evaluating post-donation outcomes in medically complex and racially diverse donors (9). In addition, there will never be randomized controlled trials comparing healthy individuals who do versus do not donate a kidney. As a result, decisions about accepting a person as a live donor depend significantly on the judgment of each transplant center's live donor team.

In the absence of high quality clinical trial data to guide decisions as to which donors are acceptable, we believe that knowledge of current practices is an important first step in guiding the formulation of donor protocols as well as future studies. While emailed surveys have potential limitations, including biases among responders, surveys often provide the best available information on practices. In this review, we highlight findings from a number of published surveys which document current practices of transplant programs in the United States.

Current US practices in donor evaluations

Donor-recipient relationships

The most striking recent trend in relationships between donors and recipients is the increased proportion of donors who are genetically unrelated. Over the past 12 years, the number of genetically related donors has not increased, while the number of genetically unrelated donors has more than doubled (figure 2). This increase is predominantly from non-spousal donors, since the percentage of donors who are spouses has remained stable over this period (1).

This trend is also reflected in surveys of US transplant program attitudes toward accepting unrelated donors. In a 1986 survey (10), only 16% of programs reported that they would accept living unrelated donors. In 2007, the authors of this review and others published a study designed to document current practices in evaluating potential donors (11) by surveying all US kidney transplant programs and the results were compared to a similar survey performed in 1995 (12). In the 1995 survey, the percentage of programs that reported they would accept living unrelated donors increased to 31%, with 8% of programs saying they would refuse to consider living unrelated donors. In 2007, 91% of programs reported performing living unrelated transplants in the prior year and for the first time, no programs said they would refuse to consider an unrelated living donor. Thus, over the past 25 years, opposition in the US to living unrelated donation has gone from strong to weak, to essentially nonexistent. There is also a trend toward increased acceptance of non-directed (altruistic or good-Samaritan) donation, from 8% of programs in 1989 (13) to 38% in 2000 (14) to 61% in 2007 (15). However, as of 2007, only 30% of US programs would consider publically solicited donors with no prior emotional connection with the recipient (15)

Age

Another important change in practices between 1995 and 2007 is in the exclusion criteria for kidney donation by age. During this period, the percentage of programs without a set upper age limit more than doubled, to 59% (11). This is reflected in a reduction in programs with other cutoffs by older age, specified in the survey as 55, 60 and 70 years old. In contrast to this less strict policy toward upper age limits, programs have become stricter with respect to younger candidates. There are no longer any programs reporting an age cutoff of 14 or 16, and almost none report having no lower age limit at all. In 2007, most programs continue to use 18-year-old as the lower age limit, although rare examples of using carefully selected minors have been reported (16). These reported practices are consistent with a recent study of the UNOS database, which found that the median age of donors increased from 35 years old in 1988 to 41 years old in 2008 (17). This study also reported that the number of living donors over the age of 65 increased from 0.7% in 1988 to 1.5% in 2008.

Kidney function

The techniques for assessing kidney function have not changed in recent years, as over 90% of programs obtain 24 urine collections for creatinine clearance (11). Fewer than 10% of programs use a direct measure of GFR, such as those based on a radioactive or iodinated marker. However, practices regarding acceptable creatinine clearance for donation have evolved between 1995 and 2007. In contrast to 1995, few programs currently report having no specific cutoff, and no programs use 40 or 60 mL/min/1.73 m². Most programs now report using 80 mL/min/1.73 m² as their cutoff, although 25% of programs now require the creatinine clearance be within two standard deviations of the mean creatinine clearance for the donor's age. The recommendation to use different creatinine clearance cut-offs depending on the age of the potential donor is based on the well-known decline in kidney function with aging, and the fact that an older donor with the same creatinine clearance as a younger donor (for example 85 mL/min/1.73 m²) has a lower chance of progressing to end-stage kidney disease. However, data regarding normal creatinine clearance for each decade of life is limited (18) and even studies using measured GFRs report somewhat different mean normal values for different ages (19–21). Therefore, significant variability likely continues to exist among US programs in their kidney function exclusion criteria for donors.

Most programs assess proteinuria using a 24 hour urine collection for protein (11). In addition, 20–30% of programs measure albumin in a 24-hour urine collection, or use a spot urine to measure either protein- or albumin-to-creatinine ratio. The measurement of albumin rather than total protein has become more widespread, in part because more recent studies have used albuminuria as a predictor of future kidney disease (22). 30mg/day of albumin is a widely accepted cut-off for microalbuminuria, but the cut-off used for proteinuria is almost as commonly 150mg/day as it is 300mg/day (11). In addition, programs will typically accept higher amounts of proteinuria if the proteinuria is demonstrated to be orthostatic. Specific definitions for hematuria also vary between programs, ranging from 3rbc/hpf to 10rbc/hpf (11). Most, but not all, programs will accept donors with hematuria if both a urological work-up and kidney biopsy are benign.

Components of the metabolic syndrome

Exclusion criteria for blood pressure appear to have become more flexible in recent years, but substantial variability exists between programs. In 1995, most programs excluded potential donors taking any antihypertensive medications and also those with borderline hypertension. In 2007, only 36% exclude borderline hypertension, 47% of programs exclude donors on any antihypertensive medication and 41% exclude donors if they are taking more than one medication (11). 8% of programs exclude donors only if taking more than two antihypertensives (figure 3). This increased acceptance of hypertension in donors may be partly due to data suggesting that donation by selected well-controlled hypertensives is safe, at least in the short term (23). Also, borderline hypertension is now more likely treated with medications (24). Untreated hypertension is clearly associated with elevated cardiovascular risk (25) and kidney disease (26), but these risks are significantly reduced with good control (27). Further data will be required to better define appropriate exclusion criteria for patients with borderline or treated hypertension.

No clear consensus has emerged regarding either screening or exclusion criteria for impaired glucose control. However, screening for glucose intolerance is generally applied more broadly in 2007 compared to 1995. Glucose tolerance testing (GTT) is currently performed by most programs for elevated fasting glucose, strong family history of diabetes or a history of gestational diabetes. In 2007, 43% of programs reported performing GTT for elevated BMI (11). Previously published practice guidelines suggest that diabetics, defined as fasting blood glucose (FBG) ≥ 126 mg/dL or 2-hr OGTT ≥ 200, should be excluded as kidney

donors (28). However, we find that the current practices are quite variable with respect to potential donors with pre-diabetes, either impaired fasting glucose (defined by the American Diabetes Association (ADA) as FBG between 100 and 126 mg/dL) or impaired glucose tolerance (defined as 2-hr OGTT between 140 and 200 mg/dL) (29). In 2007, 37% of programs used FBG over 100 mg/dL to exclude donors, while 61% exclude donors based on 2-hr OGTT over 140 mg/dL. While prior ADA guidelines for pre-diabetes and diabetes screening discouraged the use of HbA1c, the latest guidelines from 2010 (30) accept the use of FBG, OGTT and HbA1c, with a HbA1c of 5.7–6.4% used to diagnose pre-diabetes. This development suggests that programs may increase their use of HbA1c, rather than OGTT, to define risk of future diabetes, but we are not aware of any data describing such recent changes in practice. A recent review proposes an algorithm to aid in evaluation of potential living donors with impaired fasting glucose in which ethnicity, age, and features of the metabolic syndrome play a role in the decision making (31).

Transplant programs appear to pay greater attention to donor obesity in 2007 than in 1995. In the current era, 52% of programs use a BMI cutoff of 35, while 10% exclude donors with BMI over 30 (figure 4)(11). In contrast, the 1995 survey reported that only 16% excluded donors for what was called 'moderate obesity' (no BMI terms were used). Closer attention to obesity may be related to significant increases over the last few decades in the prevalence of obesity in the United States, and the increased recognition of associated morbidity and mortality (32). The negative impact of obesity on renal outcomes in the general population has been extensively described (33, 34). In addition, obesity has been shown to worsen outcomes after uninephrectomy for reasons other than kidney donation. Obese patients, defined as BMI above 30, almost universally developed proteinuria after nephrectomy, and had a much higher rate of renal failure compared to those with BMI below 30(35). Despite this, almost 20% of donors in 2008 had a BMI above 30 (17).

Practices regarding donor lipid profiles have changed little since 1995. In 2007, eight percent of survey respondents exclude donors for hyperlipidemia, 58% accept donors with hyperlipidemia and 34% have no policy (11).

Nephrolithiasis

Our survey also showed a trend for more programs accepting donors with a history of nephrolithiasis, as long as stones are no longer present and metabolic studies are normal (11). Similarly, a survey published in 2009 specifically regarding the evaluation of potential donors who have formed stones (36) showed a trend toward increased acceptance of donors with a history of kidney stones.

Genetic kidney disease

Genetic testing for polycystic kidney diseases were not available in 1995, but 25% of programs currently use genetic testing to clear donors. 90% of programs accept a donor related to a recipient with polycystic kidney disease if the donor is over 30 years old and has no cysts on radiological imaging (11).

Little consensus exists on the issue of accepting a donor with sickle trait. In a recent survey (37), 83% of transplant centers had no policy to screen donors for sickle trait. Thirty-seven percent reported excluding donors with sickle trait always or most of the time, but 47% rarely exclude and 16% never exclude those with sickle trait. High volume centers were more likely to screen for sickle trait, but not more likely to exclude potential donors with sickle trait from donating.

Flexibility in applying exclusion criteria

While transplant programs find it useful to establish protocols with numeric cutoffs for the medical tests that comprise the donor evaluation, it is clear that individual test results must often be interpreted in the context of other test results, race and age. For example, a fasting blood glucose is often interpreted in the context of the blood pressure, lipids, African heritage and age. When asked about the impact of younger donor age on how flexibly to apply criteria, programs were not flexible (figure 5A)(11). In contrast, programs were much more flexible in applying exclusion criteria when evaluating an older donor (figure 5B). This practice reflects the fact that a given risk factor for future ESRD, such as hypertension, is more of a concern for a young donor with many years at risk than for an old donor, who is much less likely to develop ESRD during the remaining years of life. Programs were not flexible in applying donor selection criteria based on the severity of the recipient's medical condition (Figure 5C), reflecting the fact that the primary goal of the donor evaluation is to do not harm, regardless of how compelling the recipient's need.

How are risks described to donors?

Despite the publication of several long-term follow up studies of donors with reassuring findings, programs generally became more cautious between 1995 and 2007 in their descriptions of donor risks. In the 2007 survey, risk of renal failure was usually described to donors as 'small' (71%) rather than 'nil' (19%), while in 1995, a much larger 64% described the risk as nil (11). The long-term risk of hypertension related to kidney donation is also now usually described as 'small' (82%) rather than 'nil' (8%), with 10% saying the risk is unknown. Similarly, the long-term risk of proteinuria is usually described as 'small' (79%) rather than 'nil' (7%), with 14% saying the risk is unknown. In 1995, a slightly lower 60–65% of programs informed potential donors that there is a 'small' risk of developing proteinuria or hypertension related to donation. These findings are consistent with the results of a different 2007 study which surveyed international programs (38).

Overall, significant variability remains among transplant programs in the criteria used to evaluate donors, and the frequency of accepting medically complex donors, defined as obesity, hypertension or eGFR <60 (39). Notably, we found no evidence that some programs are consistently strict in all their exclusion criteria, nor that other programs are consistently less strict: programs seem to determine the selection criterion for each medical test individually (11). Comparison of the 1995 and 2007 surveys suggests that programs have recently become less strict with respect to a number of exclusion criteria, including the acceptance of living unrelated and altruistic donors, older donors, hypertensive donors, and donors with a history of nephrolithiasis. However, in other areas such as younger donors, those with elevated BMI and those with low creatinine clearance, medical criteria for donation have become more restrictive. In still other areas of the medical evaluation, criteria have not become notably more or less restrictive, but more widespread or detailed testing is being applied. For example, cardiac testing and GTT appears to be applied more broadly, and new tests such as genetic testing for donors who have family members with PKD have become available.

One result of program variability in selection criteria is that motivated donors can 'shop around' for a program that will accept them. Although we have no data on how common this is, our personal experience is that it is not uncommon. We suspect that program variability will continue until further data on donor outcomes is available, especially among subsets with conditions that might affect long-term kidney function, such as older age, hypertension and glucose intolerance.

Long-term follow-up of former living kidney donors

Studies of young, healthy, Caucasian kidney donors have been reassuring about the long-term safety of living donation (6, 8). However, the proportion of medically complex donors, such as those with advanced age or a history of hypertension at the time of donation, has also increased (11, 17). Little data exist on long-term outcomes in such donors (9). As a result, many have advocated better long-term follow-up of donors, both for the individual donor's benefit and to establish databases that can be analyzed to improve the selection process for future donors (11, 12, 36). Current United Network for Organ Sharing (UNOS) policies require indefinite reporting of long-term outcomes on all recipients of organ transplants. However, UNOS policies regarding former kidney donors require less-prolonged follow-up. Since 1999, UNOS has required transplant programs to report information about living donors at postoperative discharge, 6 months, and 12 months (40). In June 2007, this reporting requirement was extended to 24 months (41). As of 2011, data requested at the yearly time points after kidney donation includes creatinine, blood pressure, use of anti-hypertensive medication, urinalysis, diagnosis of diabetes and type of treatment for diabetes.

Current follow-up practices

Despite the existence of the UNOS requirements for reporting follow-up information on former donors, many programs submit UNOS forms at the required time points, but report that the donors are lost to follow-up. To better define current practices at US transplant centers, we surveyed program directors regarding the frequency of donor follow-up, the caregiver performing the follow-up, the testing performed at follow-up, how the follow-up is paid for and what barriers exist to improved adherence with UNOS requirements (42).

All survey respondents provide postoperative care to living donors, with 99% of programs expecting to see donors at the center within 6 weeks of surgery, and the remaining 1% seeing the donors at three months (figure 6A). However, after three months, only a minority of programs expect to see donors. For example, only 30% of programs expect to see donors at the two year time point. Donor adherence to recommendations for postoperative care within six weeks is more than 90% (figure 6B). But after that, adherence to program recommendations for long-term follow-up decreases sharply with increased time from donation. At two years post-donation, only 26% of the donors at the 30% of programs recommending follow-up were seen, suggesting that fewer than 8% of all donors are seen at transplant centers at this time point. Among the programs that perform donor follow-up, surgeons provide essentially all the care in the first three months. After six months, nephrologists are slightly more likely to provide the follow-up care than surgeons.

UNOS policies require the reporting of donor data for two years after donation, but do not specify whether the care should be provided at transplant centers or elsewhere. Therefore, one potential approach to obtaining follow-up data on donors is for transplant centers to obtain that information from primary care physicians (PCPs). Seventy-eight percent of survey respondents recommended that donor follow-up care be provided by PCPs. However, these programs also reported that data on blood pressure and kidney function are rarely received from PCPs. More than half of the programs never receive any data from PCPs, and the mean proportion of donors for whom data were received was 13%. Only 5% of the programs receive data from PCPs on 75% or more of their donors (42).

Among programs that perform donor follow-up, most recommend obtaining blood pressure (87% of programs), creatinine (81%) and urinalysis (75%). Only 37% of programs check fasting blood glucose. Thus, the UNOS required data may not be uniformly requested even among programs attempting to perform donor follow-up. Approximately half of all

responding programs currently have protocols describing expected follow-up care, suggesting that many programs have not formally addressed how they will approach the monitoring of former donors.

Barriers to follow-up

In our survey (42), transplant programs identified a number of barriers to providing donor follow-up care. The most commonly reported barrier is donor inconvenience, cited by 84% of programs. Cost issues, including reimbursement to care providers, as well as direct and indirect costs to donors, are also cited by a majority of programs. Respondents also commonly reported (63%) that donors see no need for follow-up because donor health is good, and less commonly (28%) reported that programs themselves see no need for follow-up because donor health is good. Staffing demands are the least commonly reported barrier (24%).

Thus, many physicians involved in the care of living kidney donors have encountered difficulties in obtaining the post-donation information required by UNOS. Most programs do not recommend that donor follow-up be performed at their transplant centers, even at the time points up to 2 years that are required by UNOS. Even among programs that recommend follow-up at the transplant center, few former donors follow this recommendation. Many donors may be receiving routine health care maintenance from PCPs, but the information is rarely obtained by the transplant center. We suspect that as enforcement of UNOS requirements becomes stricter in future years, many donors, especially those that live far from their transplant center, will receive follow-up monitoring by local PCPs, but that the transplant centers will become more aggressive in arranging this testing and following up on the results.

Transplant programs report a wide variety of approaches to paying for long-term donor care (42). The most common method of payment is donor health insurance (58%), but respondents commented that some donors have no insurance and that many insurance companies do not cover long-term donor follow-up care. While a recent study (43) showed that 18% of US donors lack health insurance, we are unaware of documented instances in which yearly blood pressure, creatinine, glucose and urinalysis testing, such as requested by UNOS, has been denied by insurance companies. Other options for paying for donor follow-up include having donors pay out-of-pocket (25%), using transplant center funds (25%) or hospital funds (17%), billing the recipient's insurance (14%), research funds (11%), or private foundation funds (3%). Thus, donor follow-up is currently paid for by a patchwork of different approaches, many of which are unlikely to be sustainable.

Conclusions

Although living kidney donation is common in the United States, substantial variation exists among transplant programs with regards to how a potential donor is screened and which exclusion criteria are used. Some trends over the past few decades have applied to all programs, such as the use of living unrelated donors. However, screening tests and exclusion criteria for donors vary such that a donor could be readily acceptable to one program, but rejected at another. These differences reflect the absence of controlled studies or high quality long-term data on which to base exclusion criteria for potential donors. For example, no clear consensus has emerged regarding either screening or exclusion criteria for impaired glucose control in the kidney donor candidate, although screening for impaired glucose control has become more common in the last decade. US transplant programs respond to trends and outcome findings within the general population, such as increasing obesity in the US and its association with kidney failure. Many programs extrapolate the data from these general population studies, albeit imperfectly, to donor screening and exclusion protocols.

Uniformity of approach among transplant programs may increase as UNOS moves towards a more unified approach to the medical evaluation of the living kidney donor. We believe that more widespread and long-term follow-up of former living donors would provide important registry data. This data would ultimately improve the evaluation of potential living donors, especially those that are medically complex or racially diverse.

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CLINICAL SUMMARY

- Substantial variation exists among transplant centers in their protocols and exclusion criteria for potential living donors.
- Programs in the United States have become more willing to accept older kidney donors and donors who are unrelated to the recipient.
- Despite UNOS rules mandating donor follow up for two years after donation, only a minority of programs expect to see donors after three months post-donation.

Figure 1.

Trends in living versus deceased donors in the U.S. from 1998 to 2008. Note that the number of transplants performed from deceased donors was greater than the number of deceased donors, since many provide two kidneys.

Figure 2.
Trends in living related versus living unrelated donors in the U.S. between 1999 and 2008.

Figure 3. Exclusion criteria by category of blood pressure. Reprinted with permission from Mandelbrot et al. Am J Transplant 2007.

Figure 4. Exclusion criteria based on BMI. Reprinted with permission from Mandelbrot et al. Am J Transplant 2007.

Figure 5. Degree of program flexibility in the application of donor selection criteria based on A) Younger donor age, B) Older donor age and C) Severity of recipient's medical condition. Reprinted with permission from Mandelbrot et al. Am J Transplant 2007.

Figure 6.

A) Program expectations for postoperative follow-up times at the transplant center. B) For programs that recommend transplant center follow-up visits at specific times, what percentage of donors are actually seen at each time point? Reprinted with permission from Mandelbrot et al. *Transplantation* 2009.