

Practices and Barriers in Long-Term Living Kidney Donor Follow-Up: A Survey of U.S. Transplant Centers

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Background. Many have called for more comprehensive follow-up of living kidney donors, both for the donor's benefit and to establish a high-quality database of donor outcomes. United Network for Organ Sharing currently requires transplant centers to report donor follow-up information at several time points after donation, but little is known about how frequently this information is obtained, or which barriers exist to compliance with United Network for Organ Sharing requirements.

Methods. To assess practices and barriers in providing follow-up care to living donors, we sent a questionnaire to all program directors at U.S. transplant centers.

Results. Few transplant centers are currently seeing donors for long-term follow-up. Many centers recommend that donor follow-up care be provided by primary care physicians, but follow-up information is rarely received from primary care physicians. The main barriers to collecting more complete information are donor inconvenience, costs, and lack of reimbursement to the transplant center for providing follow-up care.

Conclusions. Significant changes are required to improve long-term donor follow-up by U.S. transplant centers.

Keywords: Kidney donor, Living donation, Renal transplantation.

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The increased use of living donors in kidney transplantation during the past 15 years has been well documented (1). Long-term studies of young, healthy kidney donors have been generally reassuring about the safety of living donation (2–5). However, the proportion of medically complex donors, such as those with advanced age (1) or a history of hypertension (6) at the time of donation, has also increased. Little data exist on long-term outcomes in such donors (7). 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 (7–9).

Current United Network for Organ Sharing (UNOS) policies require indefinite reporting of long-term outcomes on all recipients of organ transplants. However, UNOS poli-

cies regarding kidney donors require less-prolonged follow-up, and donors may be followed up less closely. Since 1999, UNOS has required transplant programs to report information about living donors at postoperative discharge, 6 months, and 12 months (10). In June 2007, this reporting requirement was extended to 24 months (11).

To our knowledge, practices at U.S. transplant centers regarding donor follow-up have not been described. We surveyed UNOS-registered centers regarding current practices including the frequency of follow-up, who performs the follow-up, how services are paid for, and what additional barriers exist to more complete donor follow-up. We compare current practices with UNOS regulations as well as broader calls for indefinite donor follow-up. We find that significant barriers exist to adhering to UNOS regulations and suggest that current policies should be modified.

MATERIALS AND METHODS

We designed a 19-question web-based survey to gather information about program practices regarding long-term follow-up after living kidney donation. A list of medical and surgical directors for U.S. kidney transplant centers was purchased from the UNOS. Because UNOS did not provide e-mail addresses, we searched the internet and called centers to obtain the current e-mail addresses of the medical or surgical director. We then sent e-mails describing the study purpose along with a secured hyperlink (www.surveymonkey.com) to complete the online survey. We asked respondents to provide their UNOS program code, so we could track whether multiple

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responses were received from a particular program. For the one program that had two respondents, we used the medical director's responses in the statistical analyses.

Survey responses were coded and downloaded into Statistical Package for the Social Sciences for analysis. Data are expressed as mean and SD or the percentage of centers with specific responses. Survey responses were examined by program patient volume (median split: larger vs. smaller programs), respondent specialty (nephrologist vs. surgeon), and type of center (private vs. university). Analyses included *t* tests for continuous variables, the Fisher's exact test for variables with two categories, or a two-tailed χ^2 test for variables with three or more categories.

RESULTS

Survey Responses

Of the 245 programs listed with UNOS, we were able to obtain valid e-mail addresses for 226 (92%) transplant centers. An e-mail inviting survey participation was sent to these 226 centers three times between December 19, 2007 and January 14, 2008. Eleven (5%) e-mails were returned as "undeliverable" or "error." Ninety-one programs responded, representing 40% of the programs we attempted to contact and 42% of the 215 programs that received the e-mail.

Respondent Characteristics

Similar numbers of respondents were surgeons or nephrologists, and most respondents were affiliated with a university hospital (Table 1). All the 11 UNOS regions were represented. Responding programs performed a mean of 106 kidney transplants, ranging from seven to 350 procedures. Two programs did not report volume data, so respondents represented a total of 9,422 transplants (55% of U.S. total for 2006 (1)). A mean of 42 living donor transplants were performed (range 2–185), corresponding to 3,704 transplants (58% of U.S. total for 2006 (1)). Responding programs have been performing living donor kidney transplants for an average of 25 years, ranging from 1 to 48 years of experience. Among respondents, the mean percentage of total kidney transplants performed using living donors was 36.7% and the

median was 37.6%. The proportion of U.S. kidney transplants performed from living donors in 2006 was 37.6% (1).

Program Recommendations for Postoperative Living Kidney Donor Follow-Up

All responding programs 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 3 months (Fig. 1A). A minority of programs expect to see donors after 3 months. For example, the number of programs that expect to see donors annually after 2 years drops to 20%. Donor adherence to recommendations for postoperative care within 6 weeks is more than 90% (Fig. 1B). However, adherence to program recommendations for long-term follow-up decreases sharply with greater time from donation. At 2 years postdonation, only 26% of donors at the 30% of programs recommending follow-up were seen, suggesting that less 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 3 months and somewhat less of the care at 6 months (Fig. 2). At later time points after donation, nephrologists are more likely to provide the follow-up care.

UNOS policies require the reporting of donor data for 2 years after surgery, but do not specify whether the care should be provided at transplant centers or elsewhere. Therefore, one potential solution in obtaining follow-up data on donors would be for transplant centers to obtain that information from primary care physicians (PCPs). Seventy-eight percent of survey respondents recommend that donor follow-up care be provided by PCPs, whereas 22% do not. In their comments to several questions in the survey, many centers emphasize that long-term follow-up care is usually provided by PCPs rather than transplant centers. However, the programs that recommend PCP follow-up also report that data on blood pressure and kidney function are rarely received from PCPs (Fig. 3). 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 on 75% or more of their donors.

Most programs (55%) report having the same recommendations for long-term follow-up for all donors, but these plans are modified by 24% of programs based on donor residence, 15% based on medical risk, and 1% based on psychiatric risk. Several respondents commented that donors who live far away would not be expected to come back to the transplant center for long-term follow-up.

Among programs that perform donor follow-up, the specific tests performed at the transplant center or by PCPs are shown in Fig. 4. At 1 year, most programs request a blood pressure, physical examination, creatinine, and urinalysis. Sixty-six percent measure urinary protein or albumin. Only 37% of programs check fasting blood glucose. Testing practices at later time points after donation were similar (data not shown).

Mental health evaluations are usually not included as part of routine donor follow-up, but 32% of programs report performing such evaluations when concerns arise, 10% plan follow-up evaluations if there are predonation mental health risk factors, and 2% limit these evaluations to certain donor types. Thirteen percent of programs do perform postdona-

TABLE 1. Demographics

Variable	% Respondents (N=91)
Specialty	
Nephrologist	44
Surgeon	46
Nurse	10
Type of center	
University	52
Private hospital, university affiliated	29
Private hospital, not university affiliated	20
Type of surgery	
Adult only	41
Pediatric only	4
Both adult and pediatric	55

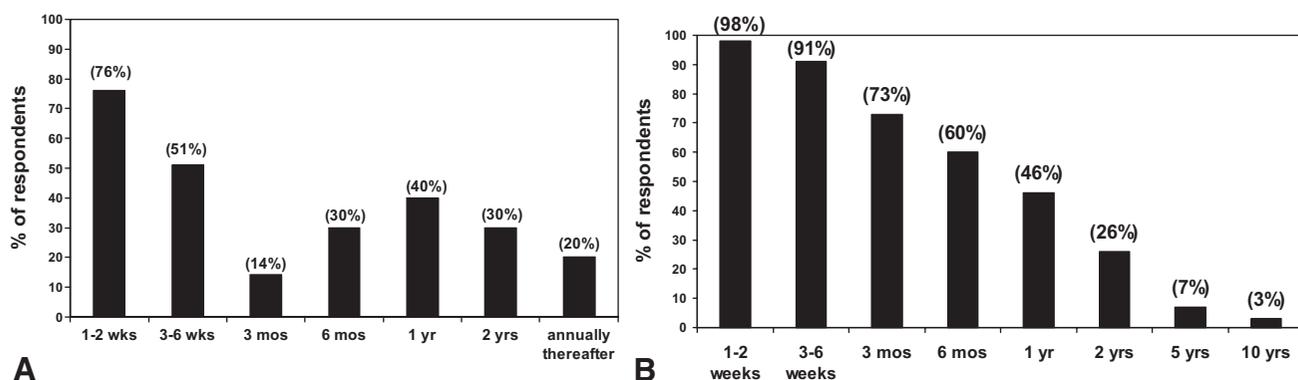


FIGURE 1. (A) Program expectations for postoperative donor follow-up times at the transplant center (n=91). (B) For programs that recommend transplant center follow-up visits at specific times, what percentage of donors are actually seen at each time point (n=91)?

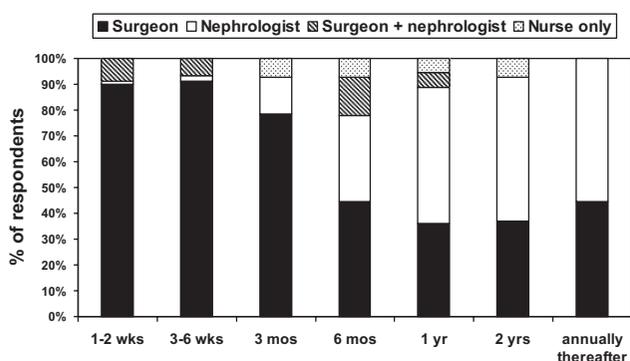


FIGURE 2. Caregiver who performs donor follow-up at the transplant center (n=91).

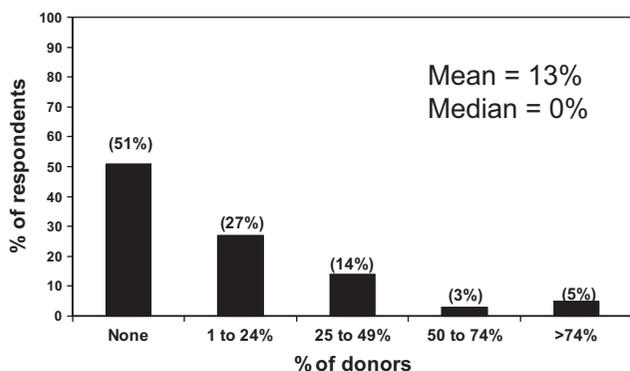


FIGURE 3. If program recommends follow-up by PCP, for what percentage of donors is data received from the PCPs on BP, kidney function, etc. (n=71)?

tion mental health evaluations on all donors, 28% rarely form such evaluations, and 21% never perform them.

Regarding written documentation of donor follow-up policies, 48% of programs report having protocols describing expected follow-up care and 48% of respondents include information about expected follow-up in their consent forms. Fifty-two percent of respondents have no written protocols and do not include information about follow-up in consent forms.

Barriers to Providing Living Donor Follow-Up

The most commonly reported barrier to providing donor follow-up is donor inconvenience, cited by 84% of programs (Fig. 5A). 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 find 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.

Transplant programs report a wide variety of approaches to paying for long-term donor care (Fig. 5b). 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. The second most common method of payment for these services is having donors pay out-of-pocket (25%) and 14% of programs report billing the recipient's insurance. The survey did not ask how often the bills sent to donor or recipient insurance were fully or partly paid. Other options for paying for long-term donor care include hospital funds, transplant center funds, research funds, and private foundation funds. Many respondents commented that they routinely write off the costs of long-term donor follow-up.

Differences in Responses Based on Program Characteristics

We hypothesized that larger programs, or programs with higher rates of living donation, might have more comprehensive donor follow-up policies and greater success in collecting follow-up data. However, we did not find statistically significant differences between large and small programs with respect to recommended frequency of donor follow-up, likelihood of getting follow-up information, recommendations to obtain information from PCPs, success in getting information from PCPs, likelihood of having written protocols describing follow-up care, or barriers to follow-up. Responses to these questions were also similar between programs with higher or lower rates of living donation. We examined the impact of program size and living donation rates both as continuous variables, and dichotomized using a median split. The only

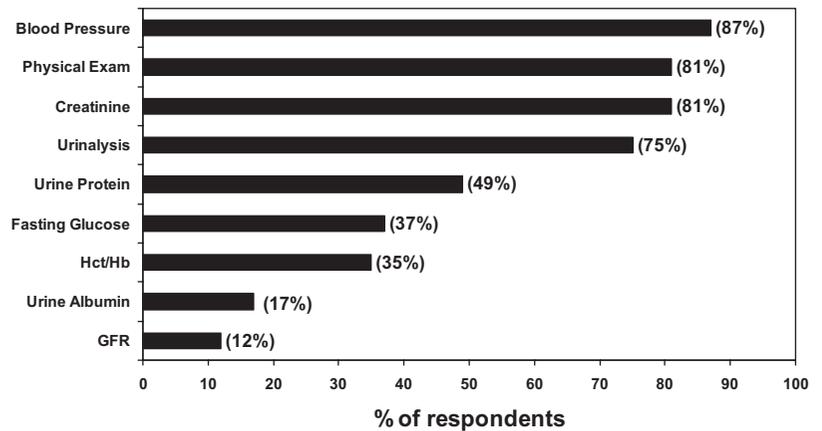


FIGURE 4. Tests requested at 1-year follow-up (n=83, more than one answer allowed).

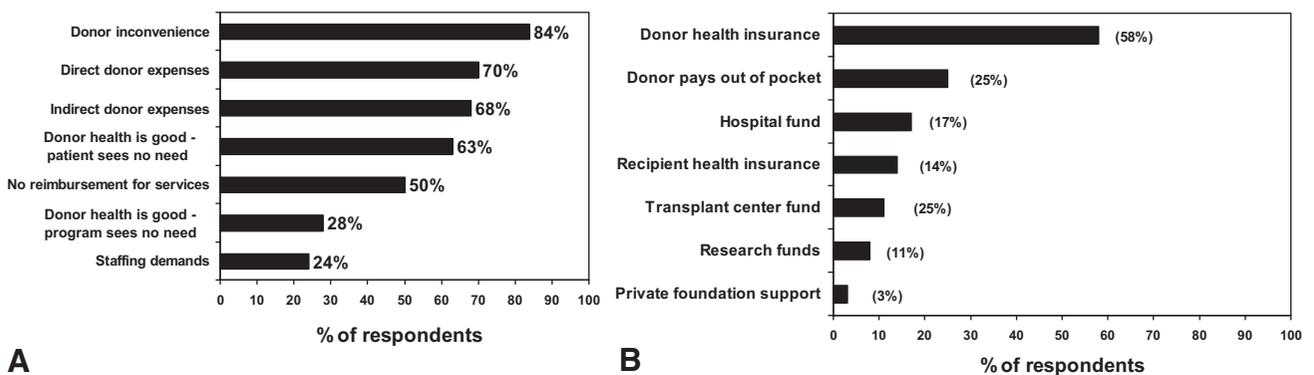


FIGURE 5. (A) Barriers to living donor follow-up medical care (n=88, more than one answer allowed). (B) If long-term care is provided by a center, how are services paid for (n=36, more than one answer allowed)?

difference in responses between surgeons and nephrologists was in citing as a barrier to follow-up that “donor health is good—the program feels no need to follow them closely.” A total of 35.7% of surgeons reported this barrier compared with 12.5% of nephrologists ($P=0.02$). The only difference in responses between private hospital programs (whether affiliated with a university or not) and university programs was in the percentage of donors seen 6 or more months after donation. For example, at 5 years, 11% of private programs and 4% of university programs ($P=0.02$) saw donors.

DISCUSSION

Many physicians involved in the care of living kidney donors have encountered difficulties in obtaining the postdonation information required by UNOS. The goal of this survey of practices in U.S. transplant centers was to document how often this information is requested, how often it is obtained, which specific tests are recommended, and the barriers to obtaining more complete information. We find that most responding 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 (Fig. 1A). Although most programs do recommend that donors follow-up regularly with their PCPs, this information is rarely received by transplant centers (Fig. 3). Some programs may be unaware of UNOS requirements, whereas others may feel that the barriers to compliance are too high to attempt donor follow-up—our survey did not distinguish between these two

possibilities. Among programs that do attempt prolonged follow-up, success in obtaining information declines continually with time, such that the number of donors seen beyond 2 years is negligible (Fig. 1b). It is possible that some programs fulfill the minimum requirement to return donor follow-up forms to UNOS by simply indicating that follow-up information is “unknown.” This response currently avoids UNOS disciplinary actions for failure to complete forms, but would not seem to meet the intent of the UNOS policy.

The U.S. Organ Procurement Transplant Network report forms (TEIDI) ask about physical capacity, work status, radiological studies, creatinine, blood pressure, medications for hypertension, urinary protein, diagnosis of diabetes, and use of diabetic medications for kidney donors at 6, 12, and 24 months postdonation. Most, but not all, survey respondents who perform donor follow-up themselves or obtain data from PCPs measure creatinine, blood pressure, and urinary protein, and only 37% measure fasting blood glucose. It may be that these tests were not reported as being performed more universally because some respondents mistakenly answered this question based on information obtained, rather than tests requested. Although most nephrologists routinely determine their patient’s proteinuria, it may be that the surgeons (Fig. 2) and PCPs who often perform donor follow-up are less focused on this measure, so it is requested less often than blood pressure or creatinine. We did find that surgeons are more likely than nephrologists to report that donor health is good, so that follow-up is not needed, and this was the only

difference between surgeons and nephrologists in multiple comparisons.

About half of the responding programs have protocols describing their recommendations for long-term donor follow-up, and a similar proportion of programs includes a description of the follow-up as a part of the consent forms. Such protocols and consent forms are not explicitly required by any transplant regulations that we are aware of, although transplant centers are required by the Centers for Medicare and Medicaid Services to have written policies "for the donor evaluation, donation, and discharge phases of living organ donation." (12) We suspect that because of overall trends toward increased regulation of living donor programs and increased requirements for written protocols for all transplant center practices, written protocols for living donor follow-up will be required in the future.

In general, U.S. transplant programs are not responding to call for widespread and prolonged follow-up of living kidney donors, nor are they satisfying UNOS goals for specific information postdonation. The most striking finding among the reported barriers to follow-up is that donor inconvenience is the most common explanation, and it is almost universally cited (Fig. 5A). This explanation is probably closely related to another commonly reported perception, namely donor health is good, so the donor or the program see no need for follow-up. Therefore, arguments that donor follow-up would benefit donors themselves, as well as contribute to the knowledge base of the field, do not seem to be commonly accepted. If a transplant center agreed that donor follow-up is important, one could argue that donor inconvenience should not be any more of a barrier to follow-up than for completing a predonation evaluation, which includes much more comprehensive testing. We suspect that with further education in the transplant community about the importance of donor follow-up, transplant centers and therefore donors will learn that the benefits of follow-up do justify the inconvenience to donors. In addition, awareness and compliance with UNOS reporting requirements are expected to increase over coming years.

Geographic distance from transplant centers was cited as an important factor in determining whether donors go to a transplant center versus a local PCP for follow-up, but donor follow-up information rarely reaches transplant centers from PCPs (Fig. 3). Although we did not specifically ask why this information is rarely obtained, our own experience suggests that this process is time and labor intensive, and therefore costly. It requires reviewing donor records for missing follow-up information, asking donors to request that specific tests be performed by PCPs, then following up to request information that was not sent, then entering the data in a transplant center database. Nevertheless, more widespread use of this approach represents a potential solution to problems with donor inconvenience.

Cost issues also have an important impact on donor follow-up. Most programs report that direct and indirect donor costs to donors, as well as lack of reimbursement for services, are barriers to follow-up (Fig. 5a). One respondent suggested that UNOS reporting requirements could be characterized as an "unfunded government mandate," because the physician time and laboratory testing required obtaining donor follow-up data are usually not reimbursed. Prolonged donor follow-up is currently paid for by a patch-

work of different approaches. Many of these approaches, such as using funds from the hospital, transplant center, research centers, and private foundations, are unlikely to be sustainable, nor would writing off these costs. Having donors pay out-of-pocket would be viewed as unacceptable, given that donors have already made a substantial and generous sacrifice in donating a kidney.

Current Medicare rules state that "Coverage of kidney donor services includes postoperative recovery services directly related to the kidney donation. The period of postoperative recovery ceases when the donor no longer exhibits symptoms related to the kidney donation. Claims for services rendered more than 3 months after donation surgery will be reviewed carefully. However, follow-up examinations may be covered up to 6 months after the donation to monitor for possible complications." (13) Therefore, we suspect that billing recipient insurance for routine donor follow-up care beyond 6 months is rarely successful and will not withstand the scrutiny of audits. Billing donor insurance is the most common approach to cover long-term donor care, and we believe that it is most likely to have widespread and long-term success. However, in the absence of substantial changes in healthcare policies, it is likely that some donors will continue not to have health insurance and some insurance companies will not reimburse long-term donor follow-up.

The validity of any questionnaire such as ours has several potential limitations. We have no way of confirming how accurately reported practices reflect actual events. In addition, 40% of programs that responded may not accurately reflect all programs in the country. However, the mean number of living donor transplants among respondents, as a proportion of all kidney transplants, was 37.6%, which is also the actual percentage of living donor kidney transplants performed the same year in the United States (1). The reported number of kidney transplants performed by respondents was 58% of the U.S. total that year, suggesting that the 40% of programs who responded are larger than average U.S. programs. This skewing may not be surprising, because larger programs may be more interested in addressing issues of transplant protocols. However, the responses in our study did not differ significantly by program size, suggesting that program size itself does not introduce a significant bias in responses. If anything, we would expect that larger programs would be more likely to have the resources and capacity to perform prolonged donor follow-up, so that our findings of limited success in performing this follow-up may underestimate the extent of the problem.

We conclude that many calls for establishing a high-quality database of long-term living donor outcomes have not been successfully answered. UNOS requirements for reporting only apply to the first 2 years postdonation, and even these are not consistently followed. Currently available data on long-term outcomes comes from single centers in the United States and several European countries that collect complete medical information on their population. For the United States to achieve widespread, long-term donor follow-up will require greater UNOS and transplant center participation. The Scientific Registry of Transplant Recipients (SRTR) is an example of a high-quality UNOS database that already exists. The SRTR has allowed unique studies to be performed and has

provided critical information on how to improve outcomes in transplantation. We suggest trying to replicate the experience of the SRTR with donors. However, this would require greater support of transplant programs to overcome the financial barriers to compliance with UNOS requirements, especially if these requirements were extended beyond 2 years of reporting. In particular, modification of Medicare rules so that donor follow-up is explicitly covered by medical insurance would make transplant center follow-up of donors much more likely. Also, having follow-up care be more commonly provided by PCPs would overcome problems with donor inconvenience and insurance reimbursement, because this care would be covered under yearly “physicals.” However, transplant centers would need novel funding mechanisms to support the staff required to obtain follow-up data from PCPs. Once these changes are instituted, it may be reasonable for UNOS to consider greater enforcement of requirements for donor follow-up.

REFERENCES

1. U.S. Department of Health and Human Services. *Annual Report of the U.S. Organ Procurement and Transplantation Network and the Scientific Registry of Transplant Recipients: Transplant Data 1995–2004*. Rockville, MD: Health Resources and Services Administration, Healthcare Systems Bureau, Division of Transplantation 2007.
2. Narkun-Burgess DM, Nolan CR, Norman JE, et al. Forty-five year follow-up after uninephrectomy. *Kidney Int* 1993; 43: 1110.
3. Fehrman-Ekholm I, Duner F, Brink B, et al. No evidence of accelerated loss of kidney function in living kidney donors: Results from a cross-sectional follow-up. *Transplantation* 2001; 72: 444.
4. Ramcharan T, Matas AJ. Long-term (20–37 years) follow-up of living kidney donors. *Am J Transplant* 2002; 2: 959.
5. Ibrahim HN, Foley R, Tan L, et al. Long-term consequences of kidney donation. *N Engl J Med* 2009; 360: 459.
6. Mandelbrot DA, Pavlakis M, Danovitch GM, et al. The medical evaluation of living kidney donors: A survey of US transplant centers. *Am J Transplant* 2007; 7: 2333.
7. Young A, Storsley L, Garg AX, et al. 2008. Health Outcomes for Living Kidney Donors with Isolated Medical Abnormalities: A Systematic Review. *Am J Transplant* 2008; 8: 1878.
8. Abecassis M, Adams M, Adams P, et al. Consensus statement on the live organ donor. *JAMA* 2000; 284: 2919.
9. Davis CL, Delmonico FL. Living-donor kidney transplantation: A review of the current practices for the live donor. *J Am Soc Nephrol* 2005; 16: 2098.
10. Living Donor Committee Board of Director’s Report to UNOS, June 2003.
11. Living Donor Committee Board of Director’s Report to UNOS, June 2007.
12. Federal Register, Rules and Regulations, section § 482.94. 2007; 72(61): 15276.
13. Medicare Benefit Policy Manual, Chapter 11—End Stage Renal Disease (ESRD) (Rev. 83, 02-15-08), Posttransplant Services Provided to Live Donor 2008, p 60.