

Evaluating Living Kidney Donors: Relationship Types, Psychosocial Criteria, and Consent Processes at US Transplant Programs

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We conducted a survey of 132 US kidney transplant programs to examine how they evaluate and select potential living kidney donors, focusing on donor-recipient relationships, psychosocial criteria, and consent processes. There is heterogeneity in donor-recipient relationships that are considered acceptable, although most programs (70%) will not consider publicly solicited donors. Most programs (75%) require a psychosocial evaluation for all potential living donors. Most programs agree that knowledge of financial reward (90%), active substance abuse (86%), and active mental health problems (76%) are absolute contraindications to donation. However, there is greater variability in how other psychosocial issues are considered in the selection process. Consent processes are highly variable across programs: donor and recipient consent for the donor evaluation is presumed in 57% and 76% of programs, respectively. The use of 13 different informed consent elements varied from 65% (alternative donation procedures) to 86% (description of evaluation, surgery and recuperative period) of programs. Forty-three percent use a 'cooling off' period. Findings demonstrate high variability in current practice regarding acceptable donor-recipient relationships, psychosocial criteria, and consent processes. Whether greater consensus should be reached on these donor evaluation practices, especially in the context of more expansive use of living donor kidney transplantation, is discussed.

Key words: Informed consent, kidney donor, living donation, psychosocial, renal transplantation

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Introduction

Once restricted to family members, live donor kidney transplants are now performed using donors who are unrelated or who may not have a pre-existing emotional relationship with the recipient (1). In addition, novel programs now facilitate the exchange of kidneys among incompatible donor-recipient pairs (2–4), with excellent outcomes (5–11). Nevertheless, ethical concerns have been raised about the expanding landscape of living donors and associated psychosocial issues (12–20). To address these concerns, consensus statements and new regulations have articulated principles that should guide the evaluation of potential living donors and their informed consent (21–26). However, the degree to which transplant programs in the US apply these principles in practice is not known. Therefore, we conducted a web-based survey of kidney transplant programs to gather information about current practices as they pertain to donor-recipient relationships, psychosocial criteria and consent processes surrounding living donor evaluation and selection. A companion article summarizes the medical evaluation and inclusion/exclusion criteria data from this same survey (27).

Materials and Methods

Mandelbrot et al. (27) provides a comprehensive description of the methods used to conduct the survey. In brief, a 56-item web-based survey was sent via email to medical and/or surgical directors of kidney transplant programs in the United States. The 1995 survey published by the Patient Care and Education Committee of the American Society of Transplant Physicians was replicated to the extent possible (28). New questions were added to examine psychosocial evaluation and informed consent. Only one response per program was included in the statistical analyses. If both the medical and surgical director from the same program responded independently to the survey, the medical director's responses were chosen for inclusion in the statistical analyses. If a program director (medical or surgical) and another member of the transplant team completed the survey, the program director's responses were used. Survey responses were examined by program patient volume (median split: larger vs. smaller programs), program type (adult only vs. pediatric only or both), and UNOS region. Analyses included *t*-tests for continuous variables, the Fisher exact test for variables with 2 categories, or a 2-tailed chi-square test for variables with 3 or more categories.

Table 1: Acceptable donor types

| Donor type | N (%) |
|--|-----------|
| Adult sibling | 132 (100) |
| Parent | 132 (100) |
| Adult child ¹ | 123 (100) |
| Spouse ¹ | 123 (100) |
| Extended family member with close emotional relationship to recipient | 132 (100) |
| Friend with close emotional relationship to recipient | 132 (100) |
| Coworker | 122 (92) |
| Extended family member without a close emotional relationship to recipient | 115 (87) |
| Member of faith community with no prior relationship with recipient | 108 (82) |
| Acquaintance without close emotional relationship to recipient | 98 (74) |
| Teacher of recipient | 95 (72) |
| Employer or supervisor of recipient | 85 (64) |
| Stranger, non-directed | 80 (61) |
| Employee or supervisee of recipient ¹ | 75 (61) |
| Person solicited <i>via</i> website, newspaper, or other media outlets | 39 (30) |

¹Centers performing only pediatric transplants were excluded from analysis.

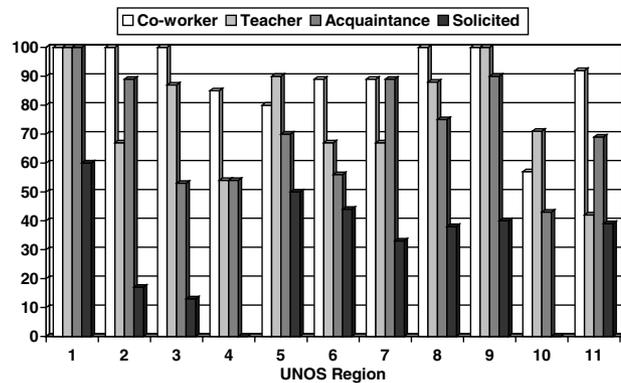
Results

Respondent and program characteristics

Respondents were 132 programs, representing 64% of those programs invited to participate in the study and 53% of all UNOS-listed programs. Medical (52%) and surgical (34%) directors completed most of the surveys. All 11 UNOS regions were represented by multiple programs. Mean number of total kidney transplants performed by the responding programs in 2005 was 93.7 ± 67.4 ($n = 10,965$, median = 83.0), deceased donor = 55.0 ± 40.3 ($n = 6436$), living related donor = 26.0 ± 24.0 ($n = 3036$), and living unrelated donor = 12.7 ± 12.9 ($n = 1484$). Using publicly available data (www.ustransplant.org), we compared survey responders and non-responders on patient volume statistics. Responders did significantly more total, deceased donor, and living donor transplants than non-responders (55.0 ± 40.4 , 31.8 ± 31.3 , 23.3 ± 28.2 , respectively—all p -values < 0.0001).

Types of donor-recipient relationships

All programs (100%) consider immediate family members, close friends and extended family members with close emotional ties to the potential recipient (Table 1). The majority of programs, but not all, consider all other donor types except those who have been solicited by website, newspaper or other media outlets. Only 30% of programs consider publicly solicited living donors. There was no significant relationship between willingness to consider certain donor types and patient volume or program type (all p -values > 0.05). However, there were significant differences by UNOS region for coworker ($p = 0.03$), teacher ($p = 0.05$),

**Figure 1:** Consideration of donor types by UNOS region.

acquaintance ($p = 0.03$) and publicly solicited ($p = 0.02$) donors (Figure 1). Region 1 was the only region in which all programs (100%) indicated a willingness to consider coworkers, teachers, and acquaintances as donors, and it was the region with the highest proportion of programs (60%) willing to consider publicly solicited donors. Programs in region 10 were least willing to consider coworkers (57%), acquaintances (43%) and publicly solicited donors (0%). Also, none of the programs in region 4 indicated a willingness to consider publicly solicited donors.

Alternative living donor programs

Nearly half (49%) of the programs offer ABO incompatible and positive cross-match donors the opportunity to participate in a paired kidney exchange program. A comparable proportion of programs (49%) do not currently participate in an exchange program, but 11 of them expect to offer this opportunity to potential donors and recipients in the next year. Comparably fewer programs (29%) offer incompatible donors an opportunity to participate in a paired-list exchange program. In a paired-list exchange, a living donor who is incompatible with their intended recipient donates to the waiting list, and the kidney is allocated as if it were from a deceased donor. In return, the patient who was not able to receive his or her living donor's kidney now moves to the top of the wait list and receives a kidney more quickly from the deceased donor pool. There was no significant relationship between participation in alternative donor programs and patient volume or program type (all p -values > 0.05). However, there were significant differences by UNOS region for participation in both paired ($p = 0.04$) and list exchange ($p = 0.001$) programs. Region 1 is the only region in which all programs (with one exception) offer both types of alternative donor programs. While there is considerable variability in paired kidney exchange program participation across regions, the vast majority of programs across most regions (except 1, 6 and 11) do not offer incompatible donors the opportunity to donate to the waiting list in exchange for their intended recipient moving up the deceased donor kidney transplant waiting list.

Table 2: Psychosocial issues and whether they are considered a contraindication (absolute, relative) to living donation or not, N (%)

| | N | Absolute | Relative | None |
|---|-----|----------|----------|----------|
| Knowledge of financial gain or reward | 131 | 118 (89) | 10 (8) | 3 (2) |
| Active substance abuse/dependence | 125 | 108 (86) | 15 (12) | 2 (2) |
| Active mental health problems or instability | 127 | 96 (76) | 31 (24) | 0 (0) |
| Desire for secondary gain | 126 | 49 (39) | 66 (52) | 11 (9) |
| Lack of disclosure to spouse/partner, or next-of-kin who may be affected most by donation | 128 | 45 (35) | 75 (59) | 8 (6) |
| Motivated primarily by desire for medical care | 125 | 38 (30) | 66 (53) | 21 (17) |
| Unrealistic expectations about donor experience | 129 | 38 (29) | 85 (66) | 6 (5) |
| History of poor adherence to health care recommendations | 127 | 28 (22) | 91 (72) | 8 (6) |
| Strained donor-recipient relationship | 126 | 28 (22) | 87 (69) | 11 (9) |
| Lack of family or social support | 129 | 26 (20) | 90 (70) | 13 (10) |
| Lack of health care coverage | 125 | 19 (15) | 53 (42) | 53 (42) |
| Donation strongly advised by faith community leaders | 127 | 17 (13) | 69 (54) | 41 (32) |
| Financial instability | 131 | 7 (5) | 94 (72) | 30 (23) |
| No history of past altruistic behaviors | 125 | 0 (0) | 21 (17) | 104 (83) |

Note: Row percentages may not add to 100 due to rounding.

Psychosocial evaluation and contraindications to living donor surgery

A mental health evaluation is required for all prospective donors by 74% of programs. Ten percent of programs require only certain types of donors (e.g. unrelated) to be seen by a mental health professional and 15% request such evaluations only when concerns are identified.

The majority of programs consider knowledge of financial gain or reward (89%), active substance abuse/dependence (86%) and active mental health problems or instability (76%) to be absolute contraindications to living donor surgery (Table 2). No other psychosocial issue was considered an absolute contraindication by the majority of programs. At least two-thirds of programs endorsed the following issues as relative contraindications: history of poor adherence to health care recommendations (72%), financial instability (72%), lack of family or social support (70%), strained donor-recipient relationship (69%) and unrealistic

expectations (66%). No history of past altruistic behaviors was not considered an absolute contraindication by any program. There was no significant relationship between ratings of psychosocial contraindications and transplant volume (all p-values > 0.05). However, adult programs were less likely than pediatric or combined programs to view lack of disclosure to family members who might be affected by the decision to be a living donor (87% vs. 98%, $p = 0.03$) and a history of poor adherence (85% vs. 97%, $p = 0.04$) as an absolute or relative contraindication to surgery. Finally, there were no regional differences (all p-values > 0.05).

History of alcohol abuse, drug abuse and cigarette smoking

Almost all programs have a policy regarding alcohol and drug abuse by potential living donors (Table 3). Few programs routinely exclude potential donors with a history of alcohol or drug abuse, opting instead to require a

Table 3: How programs evaluate living donors with alcohol or drug abuse history, N (%)

| | Alcohol abuse (n = 128) | Drug abuse (n = 121) |
|--|----------------------------|-------------------------|
| No policy | 5 (4) | 4 (3) |
| Donors with history of abuse are routinely excluded | 10 (8) | 12 (10) |
| Donors with history of abuse are considered only if abstinence period is sufficiently long | 64 (50) | 71 (59) |
| 3 months abstinence required | 4 (6) | 4 (6) |
| 6 months abstinence required | 30 (47) | 31 (44) |
| 12 months abstinence required | 20 (31) | 23 (32) |
| >12 months abstinence required | 7 (11) | 10 (14) |
| Minimum abstinence period determined by mental health professional on individual basis | 3 (5) | 3 (4) |
| Donors with history of abuse are considered only if there is documented participation in substance treatment or relapse prevention program | 44 (34) | 37 (31) |
| Donors with history of abuse are considered only if otherwise healthy | 38 (30) | 30 (25) |

Note: Column percentages do not add to 100 because respondents could select more than one response.

Table 4: How programs evaluate living donors who are current smokers, N (%)

| | |
|--|---------|
| No policy | 24 (20) |
| Current smokers are routinely excluded | 9 (7) |
| Current smokers are accepted | 42 (35) |
| Current smokers are considered as long as they commit to quitting before surgery | 43 (36) |
| Documentation (nicotine or cotinine screen) of smoking cessation is required | 2 (2) |

sufficiently long abstinence period. Most commonly, programs require 6 or 12 months abstinence, although there are some programs that require longer abstinence periods for alcohol (11%) and drugs (14%). Two programs require a 5-year abstinence period. In general, the alcohol and drug abuse abstinence periods within the same program are similar. However, 7 programs required longer abstinence periods for drug abuse than for alcohol abuse, while the opposite was found in 4 programs. Approximately one-third of programs consider adults with a past substance abuse history if they provide documentation of substance abuse or relapse prevention treatment. There was no significant relationship between how programs handled alcohol and drug abuse and patient volume, program type or region (all p-values > 0.05).

Twenty percent of programs do not have a smoking policy and only 7% routinely exclude smokers (Table 4). Most programs (71%) accept current smokers, but a third of these require that the donor commit to quitting before surgery. Only 2 programs conduct toxicology screens to verify smoking cessation.

Informed consent processes

While 30% and 19% of programs obtain written informed consent from potential donors and recipients, respectively, before proceeding with the donor evaluation, most programs have a presumptive approach to consent (Table 5). In contrast, all programs have a documented consent process prior to donor surgery, with almost all (95%) using written informed consent with living donors. There was no significant relationship between consent processes and patient volume or program type (all p-values > 0.05).

Table 5: Informed consent process for the donor evaluation and surgery, N (%)

| | Yes, written consent | Yes, verbal consent | No, consent presumed |
|--|----------------------|---------------------|----------------------|
| Do you obtain informed consent from the prospective DONOR before proceeding with the donor evaluation? | 37 (30) | 16 (13) | 70 (57) |
| Do you obtain informed consent from the prospective RECIPIENT before proceeding with the donor evaluation? | 23 (19) | 7 (6) | 93 (76) |
| Do you obtain informed consent from the DONOR before proceeding with the donor surgery? | 117 (95) | 6 (5) | 0 (0) |

Note: Row percentages may not add to 100 due to rounding.

Each individual element listed in Table 6 is included in the donor consent process at most programs. Information about the evaluation, surgery risks and complications, and follow-up care is the most commonly reported element in the consent process. Proportionately fewer programs include information about alternative treatments for the recipient (61%) and program-specific outcome data (64%). All 13 elements listed in Table 6 are included in the consent process at 42% of programs. There was no significant relationship between the inclusion/exclusion of individual consent elements and patient volume, program type, or region (all p-values > 0.05).

'Cooling-off' period

A small proportion (11%) of programs require all potential donors to exercise a 'cooling-off' period to ensure that they have adequate time to consider the information gathered during the evaluation process. However, one-third (32%) requires a 'cooling-off' period in selected cases. The majority of programs (57%) never require a 'cooling-off' period.

Discussion

Our data confirm much greater heterogeneity in the types of donor-recipient relationships considered acceptable now relative to years past (28–32). Spital (29–32) described a 'liberalization' of attitudes toward unrelated living donors over time, and this trend continues. For instance, the proportion of programs that consider non-directed (or altruistic strangers) living donors has increased from 8% in 1989 (29) to 15% in 1994 (30) to 38% in 2000 (32) to 61% in our survey. More frequent consideration of genetically unrelated donors is due to many factors, including better immunosuppression medications that have improved clinical outcomes for recipients (33), laparoscopic surgical techniques that have reduced morbidity risks for donors (34), extensive experience with spousal donors (1), favorable public attitudes toward unrelated living donation (35, 36), and the shortage of deceased donor organs (37). However, the transplant community continues to debate whether we have gone too far (15,18–20). Coworkers, strangers, emotionally distant relatives and publicly solicited donors harbor complexities that extend beyond the more traditional donor-recipient pair and require careful evaluation

Table 6: Informed consent elements that are routinely included in the consent process for potential living donors, N (%)

| | |
|--|----------|
| Description of the evaluation, surgical procedure, and recuperative period | 105 (86) |
| Potential donor surgical complications, with information on donor death rates (even if never experienced at program) | 104 (85) |
| Medical uncertainties, including potential for long-term donor complications | 98 (80) |
| Anticipated short- and long-term follow-up care | 98 (80) |
| Information on specific risks and benefits to the potential recipient | 91 (75) |
| Expected outcome of transplantation for the recipient | 90 (74) |
| Any expenses to be borne by the donor | 85 (70) |
| Potential impact of donation on donor's ability to obtain health and life insurance | 84 (69) |
| Potential impact of donation on donor's lifestyle, including ability to retain or obtain future employment | 80 (66) |
| Information on potential benefits to the donor | 81 (66) |
| Alternative donation procedures, even if available only at other transplant centers | 79 (65) |
| Center-specific statistics of donor and recipient outcomes | 78 (64) |
| Alternative treatments (other than organ replacement) available to the recipient | 75 (61) |

of motives, expectations, knowledge of risks and benefits and coercion (25). Regions with longer transplant waiting times and lower deceased organ donation rates (e.g. Region 1) may be more likely to consider these nontraditional living donors for their patients.

Paired kidney exchanges represent novel and innovative strategies to not only enhance the likelihood of transplantation for potential recipients, but to offer ABO or cross-match incompatible donors the opportunity to benefit both their intended recipient and other patients in need. About half the programs we surveyed participate in paired kidney exchanges. However, we expect participation in such programs to grow dramatically over the next few years, especially since a recent opinion by the US Department of Justice (issued by C. Kevin Marshall, Deputy Assistant Attorney General, March 28, 2007) and accompanying legislation in the US House of Representatives alleviates any concerns programs may have had about violating the National Organ Transplantation Act's (NOTA) prohibition against individuals (recipients and donors) receiving any 'valuable consideration' from living donation (38). Despite growing interest within the transplant community and by incompatible living donors (39), only a small number of transplants have been performed *via* paired kidney or list exchange programs. With the high number of patients and donors that must be registered in a paired kidney exchange program for donor-recipient matches to occur, we strongly encourage much greater participation across all regions.

Consensus Statements and federal regulations have consistently emphasized the importance of the psychosocial evaluation for all potential living donors, regardless of their relationship to the intended recipient (21–26). It is surprising, then, that only 74% of programs required all potential living donors to undergo formal psychosocial evaluation. While this compares favorably to the 46% reported by Bia et al. (28) in 1995, it is imperative that every potential living donor undergoes a comprehensive psychosocial evaluation by a mental professional (social worker, psychologist or psychiatrist) who is knowledgeable about kidney transplantation and living donation. The goals and essential compo-

nents of the psychosocial evaluation should include an assessment of competency, knowledge and understanding of donation risks and benefits, psychological functioning, motivations and expectations, the donor-recipient relationship, social support and financial stability (25,26,40–42).

On certain issues, programs are in good agreement about how psychosocial information is used in the donor selection process—we should refuse living donors who intend to benefit financially from their gift, who are actively abusing alcohol or drugs, and who are psychologically unstable, and we should not exclude those who have not accumulated a portfolio of past altruistic behaviors. However, the transplant community is less certain about how to handle other psychosocial issues, including the lack of health insurance, lack of disclosure to those who may be affected by living donation, a strained donor-recipient relationship, the desire for secondary gain, an alcohol or drug abuse history, and smoking. Such divergent views are not surprising since we lack data regarding whether these factors predict good versus poor psychosocial outcomes for living donors. Nevertheless, the transplant community should strive for greater uniformity on some of these issues. For instance, while it was silent about drug abuse, the Amsterdam Forum (22) recommended that donors with an alcohol abuse history stop drinking at least 1 month prior to surgery. This should be considered a minimum abstinence period, since heavy alcohol abuse can increase post-operative morbidity (43) and risk of acute renal failure (44). Furthermore, all programs should advise potential donors to quit smoking and inform them of their increased risks of cardiovascular disease, cancer, proteinuria and possibly renal disease (45,46). Clearly, more prospective research is needed to better inform clinical decision-making and to achieve greater consensus around these issues and others.

We found that consent for donor evaluation is often presumed by programs since the potential donor initiates the evaluation process. However, the Centers for Medicare and Medicaid Services (CMS) now requires programs to have a written consent process that informs potential donors of the evaluation procedures (26). The US

Department of Health and Human Services Advisory Committee on Transplantation (ACOT) recommends two informed consent processes for potential living donors—one for evaluation and one for surgery (47). The expanding types of potential living donors, the increasing desperation of patients and family members as waiting times lengthen, and the complexities inherent in family systems and diverse cultures necessitate that potential donors be aware of the possible risks and benefits of the donation evaluation itself. Indeed, there are inherent risks in undergoing donor evaluation, and these should be made transparent to both potential donors and their intended recipients. Such risks include the psychological repercussions of learning of one's elevated risk of a future health problem, the emotional impact of being turned down for donation, and the possibility that newly discovered health information during the evaluation process may impact current or future health and/or life insurance policies. We found that emphasis is most commonly placed on medical and surgical risks of living donation, with comparatively less attention to potential non-medical risks (e.g. financial, insurance, employment) or benefits to the donor. Donors and recipients alike would benefit from the transplant community implementing a standard consent document for living donation, and this seems more likely in light of recent CMS consent guidelines (26). We recommend that programs modify the ACOT sample consent documents to include program-specific data and to ensure adherence to applicable state laws (47).

Findings from this study are limited by self-selection biases that are inherent in any survey study. Programs that we were unable to contact or that chose not to participate may have different practice patterns than those discussed here. Although the mean number of transplants performed was greater among responders, a wide range of volume statistics was represented in our sample, and we did not find any differences in practices based on program size. Therefore, we do not believe that the practices of responding programs systematically differ from those that did not respond, although such bias is impossible to exclude in such a study.

Overall, these survey results provide a useful portrait of the current practice patterns relative to the psychosocial evaluation and selection of living kidney donors. The disparity among centers may not reflect disagreement on the principles guiding the evaluation and selection of living donors, but on the many different pathways to fulfilling these basic principles. However, it can be argued that the transplant community has an obligation to minimize differences between centers and develop a consensus on what is the minimum medical and psychological eligibility criteria for living kidney donation. Standardizing minimum eligibility criteria would provide for increased transparency to the public and consistency in the experiences of potential living donors across the country. We believe that increased transparency and consistency can only serve to

improve public opinions on transplant center donor evaluation processes and improve recipient access to living donation. We believe that a consensus on minimum eligibility criteria can be reached based on previous work done by consensus committees on living donation (22,24,25), and that these criteria should be operationalized as much as possible.

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