Meeting Report

Guidelines for the Psychosocial Evaluation of Living Unrelated Kidney Donors in the United States

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Introduction

On May 25, 2006, over 70 representatives of the North American transplant community gathered in Washington, DC, to develop guidelines for the psychosocial evaluation of prospective living kidney donors who have neither a biologic nor a longstanding emotional relationship with the transplant candidate. This conference was convened by the United Network for Organ Sharing (UNOS), in collaboration with the American Society of Transplant Surgeons and the American Society of Transplantation. The participants comprised experts in the field of living organ donation and included transplant surgeons and physicians, nurses, social workers, psychologists, psychiatrists, ethicists, medical anthropologists, public health professionals and living kidney donors.

Currently, biologically unrelated donors constitute 35% of the living kidney donors in the United States (1). Although most such donors are spouses or friends with a longstanding emotional connection to the recipient, there are increasing numbers of prospective donors with little to no preexisting relationship to the recipient. Transplant candidates may identify these individuals via the Internet, print media or word of mouth. Alternatively, prospective donors may come forward in the absence of any personal appeal from a specific transplant candidate. These individuals may volunteer for directed donation, in which a connection to the transplant candidate is established only by the donation itself. Other possibilities include nondirected donation and participation in programs of paired and list donation. Between 1996 and 2006, UNOS data show that, among living donors, the percentage who had neither a biologic nor close emotional relationship with a transplant recipient (i.e. all codes for specific types of ‘nonbiological, unrelated’ donors, including paired exchange, anonymous and directed, but excluding the code for spouses) increased from 6.5% to 23% (1).

This expansion of living donor kidney transplantation, driven in part by the continued shortage of donor organs and by well-intentioned prospective donors who are responding to this shortage, has caused concern in the medical community regarding a variety of issues...
that might arise in the context of these donations (2–10). Such issues include donor psychological status and motivation (2,4,5,9); knowledge and expectations about transplantation and donation (2,5,6) and, in some situations, the potential for undue pressure to donate and emotional and financial exploitation (4–6,8–10). Questions regarding these issues have arisen each time the pool of donors has been expanded (7,11–15). However, the current circumstances by which prospective donors with neither biologic nor longstanding emotional connections with a transplant candidate (henceforth referred to as unrelated donors) are identified differ from previous circumstances in important ways, as discussed further below. As such, they provoke significant new concerns that demand careful consideration during the donor evaluation process in order to continue to preserve donor safety and well-being.

All prospective donors, regardless of the nature of their relationship with the transplant candidate, deserve careful psychosocial and medical evaluation in order to ensure their safety (3). From a psychosocial perspective, donor safety implies a low psychosocial risk to benefit ratio. The nature of the donor-transplant candidate relationship may directly affect this psychosocial risk to benefit ratio. In particular, it has been suggested that, for unrelated donors, the potential psychosocial risks of donation are less likely to be outweighed by any benefits (5,16). Indeed, many of the benefits that typically accrue for a related donor—e.g. seeing the recipient regain health—are proposed to be lacking for most unrelated donors (2,5). Given the growing number of unrelated donors and in light of the transplant community’s obligation to provide adequate safeguards for all donors (17), conference participants were asked to specify and offer recommendations regarding:

- the characteristics of prospective unrelated donors that may either increase their risk for, or serve as protective factors against, poor donor psychosocial outcomes.
- the principles underlying the informed consent and evaluation process that are of particular pertinence for these unrelated donors.
- the process and content of the psychosocial evaluation for these donors.

As the backdrop to considering these issues, conference participants agreed to accept a series of basic facts and assumptions regarding the current status of living donation in the United States (Table 1). Many of the points in Table 1 also underlie current international recommendations for the care of living donors (18–22).

### Characteristics Serving as Risk or Protective Factors for Unrelated Donors

Conference participants listed the following current examples of types of unrelated donors that have provoked heightened concerns within the transplant community: individuals solicited from Internet or media appeals, individuals in a superior/subordinate relationship with the transplant candidate (employers/employees, teachers/students), foreign nationals, members of organizations/faith communities, individuals involved in paired and list donation, and individuals seeking to make a nondirected donation (2,3,6,8,9). The circumstances under which such individuals come forward require careful exploration, as do their motives and knowledge about donation. Conference participants agreed that pertinent examples under such circumstances include Internet web sites and media advertising that facilitate strangers learning about the needs of individual kidney transplant candidates (6,8,9). The transplant candidate may make a compelling case for the need for a kidney that not only fails to consider donor medical risks, but is worded in desperate and emotion-laden terms that evoke powerful psychological responses among the readers of these messages (6,8). In the absence of any pre-existing relationship to the candidate, a potential donor has little context in which to evaluate the request and thus may be more heavily influenced by the emotional appeal than he or she otherwise would have been (9,23). Furthermore,

### Table 1: Facts and assumptions regarding living donation in the United States

- Transplant waiting lists in the United States continue to grow and deceased donor organ transplants cannot meet the demand.
- Living organ donation has developed as an important alternative to deceased donor organ procurement.
- Living organ donation is accepted medical practice in the United States.
- Living organ donation is voluntary.
- Living kidney donation is cost-saving to the health-care system.
- Living donors do incur nonmedical expenses.
- Buying, selling or any trade in organs is illegal in the United States.
- Living donation in the United States is not limited to donor-recipient pairs in which individuals have long-standing emotional relationships or biological linkages.
- Public solicitation of living donor organs cannot be regulated or restricted in the United States, as long as no felonious or illegal activity is involved (i.e. no party knowingly acquires, receives or otherwise transfers any human organ for valuable consideration for use in human transplantation). In other words, the ways in which relationships are developed in society with respect to living donation cannot be regulated or restricted.
- The evaluation and/or determination of eligibility of potential living donors will continue to be the responsibility of the physicians, surgeons, allied health professionals and living donor programs involved with the donors.
- Living organ donation and transplantation must be undertaken with the highest possible standard of clinical care. At all stages of the evaluation and transplantation process, the donor is as legitimately considered to be a patient as the transplant recipient and thus should be afforded the same level of care and the same protections against undue risks.
the candidate may knowingly or unknowingly fail to reveal information about alternative treatments such as dialysis or deceased donor transplantation, thus exaggerating the urgency for donation. In sum, this solicitation may frame the prospective donor’s initial view about his or her personal obligation to donate and likely donation experience. Once the prospective donor has reached initial conclusions regarding the need to proceed with donation, it may then be very difficult to modify his or her views, as has been found among living related donors (14).

In contrast, in the past, prospective donors were more likely to learn about the possibility of donation as they participated in the transplant candidate’s ongoing medical care. For example, they may have attended medical appointments or been in contact with the patient’s nephrologist after dialysis was required. While prospective donors in these situations may also have decided primarily for strong personal and emotion-laden reasons to donate (14), their decisions were more likely to have been made against a backdrop of ongoing education about treatment options and potential treatment outcomes.

Conference participants agreed that there remain ongoing concerns about the potential for donors to covertly accept payment for solicited organs, or for individuals who are vulnerable by virtue of lower social or economic status to feel that they must donate (3). The potential for real or perceived pressure or intimidation due to such status differences, together with the likelihood that vulnerable individuals may consequently see only the possible benefits but not the risks of donation (24,25), emphasize the need for careful attention to the prospective donor’s knowledge, expectations and motives for donating.

Each prospective donor brings a unique set of psychosocial risk and protective factors to the donation experience. Conference participants noted that empirical evidence has linked many of these factors to poorer versus better postdonation outcomes, although the bulk of available data pertain to biologically or emotionally related donors (26–29). In the absence of data to the contrary, and based on the collective clinical experience of conference participants, it was agreed that all donors (unrelated and related) would be at increased risk for poor psychosocial outcomes as a result of donation if they possessed the set of factors listed in the right column of Table 2. Conversely, all donors would be at an advantage if they possessed the protective factors shown in the left column of the table. However, conference participants’ experience with evaluating and clinically following unrelated donors led them to conclude that several factors, shown in italics in Table 2, conferred particularly heightened risk or protective effects for prospective unrelated donors. These pertain primarily to motives, expectations about donation or the potential for financial or personal gain, and the existence of environmental stressors and poor social supports.

<p>| Table 2: Characteristics serving as risk factors for, or protective factors against, poor psychosocial outcomes in living kidney donors, with factors of heightened importance for unrelated donors in italics. |</p>
<table>
<thead>
<tr>
<th>Lower risk/protective</th>
<th>Higher risk</th>
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<tbody>
<tr>
<td>No diagnosable psychiatric disorder or significant psychiatric symptoms</td>
<td>Significant past or ongoing psychiatric symptoms or disorders</td>
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<tr>
<td>No evidence of substance abuse</td>
<td>Substance abuse or dependence</td>
</tr>
<tr>
<td>Financial resources that could cover unexpected costs</td>
<td>Limited financial capacity to manage donation (lost wages, travel, job concerns)</td>
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<tr>
<td>Health insurance</td>
<td>Lack of health insurance</td>
</tr>
<tr>
<td>Knowledgeable about potential risk and benefits to donor/recipient</td>
<td>Limited capacity to understand donor risks/recipient benefits and alternatives</td>
</tr>
<tr>
<td>Little to no ambivalence about proceeding with donation, realistic expectations about the donation experience and potential recipient outcomes</td>
<td>Increased medical risks (e.g. chronic pain conditions)</td>
</tr>
<tr>
<td>Altruistically motivated; a history of medical altruism</td>
<td>Marked ambivalence about donating, or unrealistic expectations about the donation experience and potential recipient outcomes</td>
</tr>
<tr>
<td>History of reasonable adaptation to typical life stressors, no recent significant losses/stressors</td>
<td>Motives reflecting desire for recognition, or a desire to use the donation to develop personal relationships (e.g. desire for publicity, desire for a relationship with an individual or with treatment providers)</td>
</tr>
<tr>
<td>Support from family for donation; knowledge by family of possible donation</td>
<td>Multiple family stressors/obligations/concerns</td>
</tr>
<tr>
<td>Subordinate relationship (e.g. employee/employer) or other evidence of coercion</td>
<td>Subordinate relationship (e.g. employee/employer) or other evidence of coercion</td>
</tr>
<tr>
<td>Evidence of, or expectation of, secondary gain (e.g. avoidance of military duty, financial support from recipient)</td>
<td>Evidence of, or expectation of, secondary gain (e.g. avoidance of military duty, financial support from recipient)</td>
</tr>
<tr>
<td>Support from family for donation; knowledge by family of possible donation</td>
<td>Poor relationship with family; poor family support for donation</td>
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**Principles Underlying Informed Consent and Psychosocial Evaluation for the Unrelated Donor**

Conference participants affirmed that the basic principles governing prospective living donor informed consent and the process of evaluation, as delineated in previous
Consensus Statements (19–22), are applicable no matter what type of relationship the prospective donor has to the transplant candidate and no matter what the risk or protective factors present in the donor. Nevertheless, concerns that the psychosocial risk to benefit ratio may be less favorable in unrelated than related donors (5,16) led conference participants to reevaluate the principles in order to ensure that those principles fully address unique issues arising in unrelated donation.

Table 3 lists the basic principles, including the revisions recommended at the conference. For example, novel forms of donor solicitation (e.g. via the Internet) point to the need to ascertain that the prospective donor was not pressured to come forward (principle 1c) and does not expect financial gain (principle 1h) (3). The need to ensure that unrelated donors receive complete psychosocial evaluation to ensure their safety and informed consent led to the revisions of principles 1e and 1f. With respect to informed consent, the use of procedures to maximize understanding of information presented, including an assessment of whether the donor can verbalize his/her comprehension of risks and benefits, is required (30). Because some donors may be donating anonymously (e.g. in nondirected, paired and list donation) or may have only limited social connections with the transplant candidate, there must be heightened attention to the maintenance of confidentiality of information regarding the transplant candidate/recipient (principle 1g) (30). For similar reasons it must be recognized, as noted above, that the potential benefits to the unrelated donor may be substantially lower than in situations of long-standing relationships (5,16). Nevertheless, the potential for benefit remains, as evidenced by research on anonymous bone marrow donation and medical volunteerism in other contexts (29), as well as by the small literature on unrelated kidney donors (13). These considerations (possible benefits but a reduced likelihood thereof) led conference participants to recommend that principle 3 be modified from requiring that benefits ‘must’ outweigh the risks to a statement that the benefits ‘should’ outweigh the risks.

US transplant centers vary widely in their degree and duration of donor follow-up. Although empirical evidence suggests that donor psychosocial outcomes are favorable in the great majority of living donors (26–29), this evidence is based largely on biologically or emotionally related donors. The relative dearth of evidence on outcomes for unrelated donors led conference participants to agree that a minimum standard for clinical follow-up care, encompassing at least the first year postdonation, is essential for ensuring optimal donor psychosocial outcomes and identifying adverse outcomes in a timely manner. Conference participants recognized that many transplant programs’ limitations in resources would likely preclude routine monitoring of donor psychosocial outcomes beyond the first year postdonation and recommended that transplant programs seek research funding to systematically examine very long-term outcomes, especially in light of recent National Institutes of Health initiatives in this area (31).

Conference participants agreed that whether clinical follow-up care during the first year postdonation should be pursued by the transplant program or by the unrelated donor’s local primary care provider should be a matter of mutual agreement reached prior to the donation between the program and the donor. Any agreement that only local care would be pursued would include understanding that the transplant program would consult the local provider in order to monitor the donor’s status. A key factor to be discussed before reaching agreement about the location of care would be the donor’s ability to cover financial costs associated with repeated returns to the transplant center (since many programs accept donors who reside long distances from the center). There was strong consensus among conference participants that the transplant program should ensure that donors do not incur out-of-pocket costs for recommended follow-up care.

### Psychosocial Evaluation Process for the Unrelated Donor

The unrelated donor’s psychosocial evaluation should be guided by the following primary goals (5,22,26,32):

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**Table 3:** Recommended revisions of basic principles underlying living kidney donation

<table>
<thead>
<tr>
<th>Principle</th>
<th>Revised Statement</th>
</tr>
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<tbody>
<tr>
<td>1. A.</td>
<td>Capable of making the decision to donate.</td>
</tr>
<tr>
<td>1. B.</td>
<td>Willing to donate.</td>
</tr>
<tr>
<td>1. C.</td>
<td>Free of coercion, manipulation or undue solicitation by any party regarding the decision to donate.</td>
</tr>
<tr>
<td>1. D.</td>
<td>Medically suitable to donate.</td>
</tr>
<tr>
<td>1. E.</td>
<td>Psychosocially suitable to donate, based on an evaluation that includes a series of specific components (enumerated in Table 4).</td>
</tr>
<tr>
<td>1. F.</td>
<td>Fully informed of the risks and benefits, as demonstrated by the donor’s expression of understanding of these risks and benefits.</td>
</tr>
<tr>
<td>1. G.</td>
<td>Fully informed of the risks, benefit and alternative treatment available to the recipient, within the constraints of the transplant center’s obligation to maintain confidentiality of recipient medical information.</td>
</tr>
<tr>
<td>1. H.</td>
<td>Willing to sign a statement attesting that the donor is not providing the organ for monetary gain.</td>
</tr>
</tbody>
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1 Italized text represents revisions to the original principles published in earlier Consensus Statements about living donors (21,22).
To identify and appraise any potential psychosocial risks for a poor psychosocial outcome, including risks related to the individual’s psychiatric history or social stability.

To ensure that the prospective donor comprehends the risks, benefits and potential outcome of the donation for herself or himself and the recipient, and that the donor understands that data on long-term donor psychosocial outcomes continue to be sparse.

To assess the donor’s capacity to make the decision to donate and ability to cope with major surgery and related stresses.

To assess donor motives and the degree to which the donation decision is made free of guilt, undue pressure, enticements or impulsive responses.

To review lifestyle circumstances (e.g. employment, family relationships) that might be affected by donation.

To determine that support systems are in place and ensure a realistic plan for donation and recovery, with adequate social, emotional and financial support and resources.

To identify any factors that warrant educational or therapeutic intervention before donation can be undertaken.

In order to maximize prospective donor safety, it was recommended that a two-phase psychosocial evaluation process be followed (21,22,30,33–35):

**Phase I: Initial screening**
Once a prospective unrelated donor has contacted the transplant center or organ procurement organization, general screening questions about medical history, connection (if any) with the transplant candidate, and reasons for and expectations about donation should be reviewed, usually via telephone. The prospective donor’s knowledge of basic facts about the risks involved in surgery and recovery would also be examined so that he or she would be able to make an informed choice about continuing to Phase II. Lack of knowledge would not necessarily preclude donation, but would allow for further education. If the transplant team uncovered overriding indications that a prospective donor should not be considered further for donation (e.g. current substance dependence; evidence of undue pressure to donate; see Table 2), a decision could be made that more extensive psychosocial and medical evaluation should not be undertaken. The prospective donor should be provided with an explanation, as well as referrals should she or he desire another opinion or need further help. Otherwise, if the prospective donor remains interested in donation and if any additional medical screening was negative, Phase II would be undertaken.

**Phase II: On-site evaluation**
Conference participants agreed that a detailed on-site psychosocial evaluation is mandatory for all prospective unrelated donors. Several guidelines for comprehensive psychosocial evaluations of prospective donors (both related and unrelated) have been published (2,5,22,29,32); these underlie conference participants’ recommendations.

The psychosocial evaluation and the decision to accept an unrelated donor should take place at the center where the donor surgery will take place (with the exception that programs of paired donation may conduct the evaluation and accept the donor at the donor’s ‘local’ center before he or she enters the matching system). The evaluation should be conducted early during the course of the prospective donor’s complete medical evaluation, so that invasive medical examinations could be avoided if clear psychosocial contraindications were apparent. In addition, conference participants agreed that a donor should initially be interviewed alone. An additional interview or telephone conversation that included both the prospective donor and his or her significant other was also recommended.

Consistent with accepted principles for the donor evaluation process (2,21,22), the psychosocial evaluation should be carried out by one or more members of an independent donor team (i.e. entirely separate from the transplant candidate’s team). For programs lacking the resources to support a separate donor team, the evaluation should be conducted by an external consultant who is not a member of the transplant team (in order to ensure an evaluation independent of the competing interests of the transplant candidate) and who serves as the donor advocate (22). There should be a donor ‘cooling off’ period after the Phase II evaluation in order to ensure that the decision to donate has been adequately considered by the prospective unrelated donor. The duration of this period should be at the discretion of the donor team (or independent evaluator) but should generally be at least 2 weeks.

Table 4 lists the essential components of the psychosocial evaluation interview. The interview should focus on any elements directly related to the individual’s unique circumstances at the time of donation. For example, the donor-recipient relationship (if any) will likely affect the depth of consideration of certain components, with more extensive evaluation required if no previous relationship exists (2,5).

In order to address the need to cover multiple separate components, with selective depth in some areas, conference participants agreed that the interview should be conducted in two separate sessions. The first session would address each of the components and would be conducted by a clinical social worker, nurse specialist or other similarly trained allied health-care professional. Any areas of concern would be evaluated more extensively, along with further psychological examination, during the second session, which should be conducted by a psychologist or psychiatrist.
Financial suitability:

Social support:

Donor knowledge, understanding and preparation:

Motivation:

Psychological status:

Capacity:

History and current status: Obtain standard background information regarding such areas as the prospective donor’s educational level, living situation, cultural background, religious beliefs and practices, significant relationships, family psychosocial history, employment, lifestyle, community activities, legal offense history and citizenship.

Capacity: Ensure that the prospective donor’s cognitive status and capacity to comprehend information are not compromised and do not interfere with judgment; determine risk for exploitation.

Psychological status: Establish the presence or absence of current and prior psychiatric disorder, including but not limited to mood, anxiety, substance use and personality disorders. Review current or prior therapeutic interventions (counseling, medications), physical, psychological or sexual abuse, current stressors (e.g. relationships, home, work), recent losses, chronic pain management. Assess repertoire of coping skills to manage previous life or health-related stressors.

Relationship with the transplant candidate: Review the nature and degree of closeness (if any) to the recipient, e.g. how the relationship developed; and whether the transplant would impose expectations or perceived obligations on the part of either the donor or the recipient.

Motivation: Explore the rationale and reasoning for volunteering to donate, i.e. the ‘voluntariness’, including whether donation would be consistent with past behaviors, apparent values, beliefs, moral obligations or lifestyle, and whether it would be free of coercion, inducements, ambivalence, impulsivity or ulterior motives (e.g. to atone or gain approval, to stabilize self-image, to remedy psychological malady).

Donor knowledge, understanding and preparation: Explore the prospective donor’s awareness of any potential short- and long-term risks for surgical complications and health outcomes, both for the donor and the transplant candidate; recovery and recuperation time; availability of alternative treatments for the transplant candidate; financial ramifications (including possible insurance risk). Determine that the donor understands that data on long-term donor health and psychosocial outcomes continue to be sparse. Assess the prospective donor’s understanding, acceptance and respect for the specific donor protocol, e.g. willingness to accept potential lack of communication from the recipient; willingness to undergo future donor follow-up.

Social support: Evaluate significant other, familial, social and employer support networks available to the prospective donor on an ongoing basis as well as during the donor’s recovery from surgery.

Financial suitability: Determine whether the prospective donor is financially stable and free of financial hardship; has resources available to cover financial obligations for expected and unexpected donation-related expenses; is able to withstand time away from work or established role, including unplanned extended recovery time; has disability and health insurance.

Conclusions

Living kidney donation has traditionally provided an opportunity for individuals to express their caring for suffering family members or close friends. It now allows for the expression of compassion and altruism toward unrelated individuals facing the prospect of renal failure. The solicitation of unrelated living donors through the media, Internet and other forms of communication has led to more careful scrutiny of prospective donors, as ongoing efforts such as those described herein are made to ensure that unrelated donors are knowledgeable and have minimal psychosocial risks. The safety and well-being of each donor will be maximized only by considering (a) the unique circumstances that led the individual to come forward for donation and (b) the unique set of psychosocial risk and protective factors that the individual brings. This report has delineated elements of both the circumstances and the nature of psychosocial risk and protective factors that must be considered when evaluating unrelated prospective donors. The guidelines offered herein regarding the principles and the specific process and content of the psychosocial evaluation will ensure that unrelated donors are afforded as careful and complete consideration as that provided to any other living donor.

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The Living Unrelated Kidney Donor

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17. Letter from Dr. James F. Burdick, director, Division of Transplantation, Healthcare Systems Bureau, Health Resources and Services Administration, Department of Health and Human Services, to Walter K. Graham, Executive Director, United Network for Organ Sharing, October 29, 2004.


