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**FORUM** 

# THE NONDIRECTED LIVE-KIDNEY DONOR: ETHICAL CONSIDERATIONS AND PRACTICE GUIDELINES

# A NATIONAL CONFERENCE REPORT $^1$

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Authors, Participants of the National Conference, and Affiliations are listed at the end of this article (see Appendix).

Background. The success of kidney transplantation from a genetically unrelated living spouse or friend has influenced transplant physicians to consider the requests of individuals wishing to volunteer to be a kidney donor who have no intended recipient specified. Representatives of the transplant community gathered in Boston, MA, on May 31, 2001, to deliberate on the experience of live kidney donation from such volunteers, currently termed nondirected donors (NDD).

Objective of Conference Participants. The objective of the conference was to recommend ethical and practice guidelines for health care professionals considering the transplantation of a kidney from a live NDD.

Conference Participants. This conference was convened under the sponsorship of The National Kidney Foundation, with representation from The American Society of Transplantation and The American Society of Transplant Surgeons, The American Society of Nephrology, The United Resource Networks, The United Network for Organ Sharing, The Association of Organ Procurement Organizations, The National Institutes of Health, and The Division of Transplantation of the Health Resources and Services Administration (see Appendix).

Conference Report. The suggested content of screening interviews, which provide information regarding the donation process, elicits pertinent medical and psychosocial history, and assesses NDD motivation are presented in this report. Approaches to identifying the center that would evaluate the suitability of the

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NDD, to performing the kidney recovery, and to selecting the NDD recipient are also proposed. Other ethical issues such as the use of prisoners as an NDD, compensation for the NDD, media involvement, and communication between the NDD and recipient are discussed.

Conclusion. The willingness of health care professionals to consider NDD volunteers is driven by the compelling need to provide organs for an ever-expanding list of patients awaiting a kidney transplant. However, the psychological impact and emotional reward of donation has yet to be determined for NDD who may not have any relationship to the recipient or knowledge of the recipient's outcome. Transplant centers that accept NDD should document an informed consent process that details donor risks, assures donor safety, and determines that the goals and expectations of the NDD and the recipient can be realized.

### INTRODUCTION

The transplantation of a kidney from a living donor has evolved in the past 50 years from the limitation of requiring an identical twin to the selection of a human leukocyte antigen (HLA)-matched family member, and to the current consideration of any person willing to be an organ donor who is competent, free of coercion, and found to be medically and psychosocially suitable (1). An excellent HLA match between the donor and recipient is no longer required to achieve a successful outcome, and this has led to an acceptance of kidneys from live donors who are genetically unrelated to the recipients. The projected half-life (16 years) of a kidney transplanted from a spouse or friend who may be HLA-mismatched with the recipient (which currently includes 20% of live-donor kidney transplants) compares favorably with a transplant performed from a matched haploid-identical parent or sibling (2). This success of kidney transplantation has created an unprecedented demand for a limited supply of donor organs. It is now evident that the annual number of available, deceased donors will not resolve the ongoing organ shortage. Further, the significant mortality that occurs for candidates awaiting an organ transplant neces-

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sitates the consideration of every possibility of live-organ donation (3). The needs of transplant recipients however, do not outweigh the priority of the long-term health of organ donors. Concern for donor health, defined in the broadest sense from a medical and psychological perspective, is a pivotal ethical consideration when physicians subject healthy individuals to a procedure that has medical risks.

For years, transplant professionals have received occasional inquiries from individuals seeking to donate a kidney, without specifying an intended recipient or directing the selection of the recipient (4). The typical response of the transplant center was to consider such a request from a nondirected donor (NDD) as a gracious display of altruism; however, because there was no emotional connection between the donor and recipient, transplant physicians did not entertain this type of donation. Nevertheless, the excellent results of kidney function from living-unrelated donors and the persistent shortage of cadaver-donor organs have changed what was a routinely dismissive reply to the NDD request to a reasonable consideration (5). Advances in donor operative techniques have reduced the length of hospital stay and permitted the patient an earlier return to a normal lifestyle. These developments have enhanced the opportunity for nondirected donation as a potential donor option (6). In addition, volunteers desire reasons why they should not be considered to donate to a stranger when such compelling data support donation. This convergence of an improved outcome and a compelling need to provide suitable kidneys for an everexpanding waiting list became the impetus to examine the ethical and psychosocial issues for practice guidelines when considering NDD.

#### National Conference on the Nondirected Live-Organ Donor

Representatives of the transplant community gathered in Boston on May 31, 2001, to deliberate the existing practice and future direction of nondirected donation. The conference was convened under the sponsorship of The National Kidney Foundation (NKF), with representation from The American Society of Transplantation, The American Society of Transplant Surgeons, The American Society of Nephrology, The United Resource Networks, The United Network for Organ Sharing (UNOS), The Association of Organ Procurement Organizations, The National Institutes of Health, and The Division of Transplantation of the Health Resources and Services Administration (HRSA). The expertise and diversity of the participants included the presidents of the societies, directors of the organizations, prominent ethicists, clergy, physicians, nurses, health care professionals, social workers, and scientists. The composition of the group was carefully selected by the conference planners to include those not involved in the recipient's care, (ethicists, researchers, and donor advocates) to balance any potential bias toward promoting transplantation on behalf of recipients. Most attendants had not yet participated in nondirected donation, and most of the institutions had denied such donors to date. However, because the number of individuals volunteering to donate to a complete stranger seems to have increased (as a result of the Internet and other forms of donor education), the panel found it necessary to further examine the nondirected donation option. Programs of nondirected donation are underway at several locations on a limited basis. The number of transplant centers was not known to conference participants;

however, the number was informally thought to involve perhaps a dozen centers throughout the country.

The objectives of the conference included sharing of recent experience and developing recommendations for those who have expressed interest but have not yet established an non-directed donation program. Another objective of the NDD conference was to produce a published resource to provide information for the professional who initially responds to a potential NDD. The goal was not to authorize nondirected donation as a suitable or unsuitable practice but to provide a forum for open discussion about factors that centers should examine when considering an NDD volunteer. Conference participants focused exclusively on the issues surrounding nondirected donation of a kidney (versus other organ transplants).

#### Directed Versus Nondirected Donation

A directed organ donor has an established relationship or familiarity with an identified transplant recipient. The directed donor could be a genetically related family member (i.e., sibling, parent,) or a genetically unrelated individual (i.e., spouse, friend, acquaintance, or another person who has an emotional bond or rapport with the recipient). In rare instances, a directed donor may know of a particular recipient in need of a donated organ and only develop a relationship with that recipient for the purpose of the transplant (e.g., church members, individuals who respond to public or media notice). These donors have been accepted if they are medically and psychosocially suitable. In contrast, the NDD volunteers to donate an organ for a recipient that he or she does not know or select (5). The recipient, in effect, is a "stranger." Thus, media reports and some potential donors have used the term "good samaritan donor" to convey the novel concept and charity of nondirected donation.

# Meeting Agenda

The conference participants deliberated on the process of nondirected donation. Agenda items included the initial screening interview, identifying the transplant center, determining the medical and psychosocial suitability of the donor, selecting the recipient for the NDD, and other controversial issues such as monetary compensation for the NDD, the prisoner as a potential NDD, and media advertising by the transplant center.

#### The Process of Nondirected Donation

Transplant centers across the country are receiving inquiries from individuals who want to donate a kidney to a complete stranger. The initial inquiry from a person seeking to become an NDD may come by Internet, mail, or telephone. Conference participants also acknowledged the existence of some transplant center web sites and media advertising regarding nondirected donation, including the distribution of an educational brochure about nondirected donation by an organ procurement organization (OPO). However, it was agreed that interest in donating a kidney should be initiated by the potential NDD rather than solicited by a transplant center or OPO.

The health care professional responding to this inquiry must be a medically sophisticated person who can provide consistent and reliable information about the practice of nondirected donation. The responses to the NDD should be given in an unbiased way, without a conflict of interest (i.e., not associated with a potential recipient). An educational packet for donors should be provided by a relevant professional organization about the experience of being a live-kidney donor, in conjunction with a preliminary interview by a professional. The packet should contain a comprehensive medical and social history form that presents information to rule out the unsuitable NDD candidate before a more detailed evaluation is performed. A mechanism for the prospective volunteer donor to correspond with previous donors, directly or indirectly, may be useful, through video interviews of kidney donors or by direct communication through the transplant center or Internet. Such resources are available on request from the NKF.

#### Initial Screening

An initial interview between an informed transplant professional and a potential NDD may occur either in person or, more commonly, by telephone. The screening interview should accomplish at least three objectives. First, it should provide basic information regarding the donation process, including evaluation, operation, recovery time, potential donor costs, and long-term implications. Second, the interview should elicit a pertinent medical and social history from the potential NDD that might influence candidacy (i.e., obvious contraindications to donation). Third, the interview should initiate a discussion of the donor's motivation and capacity to comprehend the donor process. Thus, a consistent format of the initial interview was recommended by the conference participants to accomplish three objectives: medical or personal history, knowledge of nondirected donation, and donorrelated issues (see Table 1).

Many who inquire about nondirected donation have only a limited understanding of these issues and, on learning these basic realities, withdraw from the process (6). In the experience of the University of Minnesota (as of April 2001), of 142 individuals who expressed an initial interest in nondirected donation, 85 (60%) made no further contact with the transplant center after receipt of the educational information or discussion about NDD with the center staff (7). Satisfactory completion of this initial screening should result in the referral of the potential donor to a nearby transplant center or OPO that has an established program of nondirected donation (either by having its NDD protocol in place or having performed a transplant from an NDD) for a more comprehensive evaluation.

#### Identifying the Transplant Center

The initial interviewer must serve as a facilitator in the process by identifying transplant centers or OPO that are located geographically near the potential NDD and that have an established NDD program. An NDD should not be burdened or obligated to travel long distances or to incur unnecessary expenses to donate an organ; for that reason, and to provide easy access to postoperative care and social supports, it makes sense for a nondirected donation to be performed at a transplant center near the donor's home.

Thus far, there have been two models for nondirected donation. Initial efforts have occurred primarily through individual transplant centers (6). These centers have developed

#### TABLE 1. The initial screening interview

#### Medical/Personal History

- How old are you?
- Are you healthy and physically fit?
- Do you have a history of cancer, heart disease, diabetes, kidney disease, or high blood pressure?
- Do you take medications?
- Have you undergone any previous operations?
- Is there a history of kidney disease in your family?
- Do you receive disability benefits for any reason? (This does not rule out a donor a priori who should not be discouraged to proceed. They should be asked to elaborate.)
- Do you live alone? Are you married?
- Where do you live? (This will affect costs and convenience associated with donation.)

#### Knowledge About Nondirected Donation

- How did you learn or hear about organ donation?
- Do you understand that donating a kidney is not like donating blood?
- Are you aware that the risks of donating a kidney include the possibility of dying?
- Do you understand that there are risks to the recipient (i.e. that the kidney may be rejected)?
- Do you understand that you cannot be paid money for being a donor?
- Are you aware that several months may be necessary to determine your suitability as a donor by required clinical and psychological testing?
- Do you understand that you will not select your recipient and that he or she will be from the list of those who are already waiting?

#### Donor Related Questions

- Why do you wish to donate a kidney?
- Have you told a member of your family that you wish to be a kidney donor?
- Have you and your family considered the burdens associated with donation that could include out of pocket expenses for travel, doctor appointments, and time out of work?
- Is there a specific time frame to have your donor surgery performed?
- Would somebody be available to assist you at home during your recovery from surgery?

protocols that define comprehensive psychological and medical evaluation of the potential NDD and an objective process for selecting a recipient among those awaiting transplantation at their center. Another approach using an OPO was developed by the seven transplant centers comprising the Washington Regional Transplant Consortium (WRTC), in Washington, D.C. All inquiries are referred to WRTC, where the initial screening occurs by telephone. A potential NDD can then choose the participating hospital in which to undergo donor evaluation. A recipient is selected by a "match run" of the OPO's waiting list, having the transplant performed at the center with the highest ranking candidate from all participating centers. Thus, the recovery and transplant may occur at two separate hospitals in Washington, D.C, an approach made possible with minimal cold ischemia time by the proximity of participating WRTC centers.

If the NDD initially contacts a more neutral entity (i.e., an OPO, UNOS, NKF, or a private physician), it seems reasonable to refer the volunteer to the nearest transplant center with a nondirected donation program so that the individual is least inconvenienced by travel. A potential NDD might also

make his or her own choice based on personal preference, in consultation with his or her physician, or from additional personal investigation of transplant programs. Statistics and information regarding transplant center performance and experience are readily available to those who desire such additional information.

The point of these deliberations was to affirm that a prospective system should be established that avoids the appearance of center bias or manipulation. Responsibility for the comprehensive evaluation of a potential NDD, to include assessment of both medical and psychological suitability, must reside with the center that will perform the kidney recovery. As noted earlier, the donor evaluation process should be consistent with the principles outlined in the *Consensus Statement on the Live Organ Donor*, and should include the participation of an independent donor advocate (1).

#### Determining Medical Suitability

The criteria of medical suitability for kidney donation apply equally for the NDD and for the directed donor (1, 8). The NDD should be in good health, with normal blood pressure and without the necessity of antihypertensive medication, and have no history of cardiovascular disease or abnormality of renal function. The radiographic assessment of both kidneys should be normal after determining that kidney function is normal. An NDD candidate with a medical history of malignancy (except for certain types of cutaneous cancer, or a remote history of a cured malignancy) should not be accepted. The social history of an NDD must be carefully considered to avoid the transmission of infectious disease to a transplant recipient, as is done with all other living and deceased donors.

There may be an acceptable NDD who is older than 60 years; however, a minor (defined as a person less than 18 years of age) should not be an NDD because of his or her inability to provide informed consent (9). In the experience of the University of Minnesota, of 142 individuals who expressed an interest in nondirected donation, 38 (27%) were evaluated and found to be unacceptable. Twenty-three (60%) of those denied were because of medical unsuitability (7). Many years of follow-up have confirmed the medical safety and psychological benefits of directed donation. However, any new population of patients being considered as donors requires that their short- and long-term risks and benefits be established.

#### Determining Psychological Suitability

Additional emphasis was also given to the psychosocial evaluation of the NDD because there is little data on the psychological outcomes of the NDD after donation. Spital has reviewed the early experience of Sadler et al. (4), who reported nondirected donation from over 30 individuals between 1971 and 1973, most of whom were responding to a public appeal for organ donation (A. Spital, M.D., personal communication, 2001). Sadler concluded that donation from altruistic strangers was an acceptable practice, while recognizing that the number of individuals suitable for such a donation would be small.

At a minimum, a comprehensive psychosocial evaluation should be conducted by a qualified mental health professional, who must consider the same issues as for directed donation (1). The psychological status of the volunteer donor must not be compromised to a degree that would interfere with the ability to fully comprehend both the potential risks and the recovery process involved when donating. If assessment of the donor reveals psychopathology, severe mental illness, or donor vulnerability that may impair judgment, further referral for appropriate intervention is necessary, and the individual should not be considered as a potential donor. Of the 38 denied at the University of Minnesota, 8 (21%) were denied for psychosocial reasons (7).

Nevertheless, additional psychosocial scrutiny of the NDD before and after surgery is necessary because there are no data yet available that describe similarities or differences between the directed and nondirected donation experience. In directed donation, there is a defined benefit for the donor who has knowledge of and observes a family member or loved one regain health. Whereas most in the transplant community also view the directed donor as performing an altruistic act, it is well known that because of the nature of family dynamics or relationships, some family members may feel pressured to donate. The motives of the NDD are, presumably, more heavily weighted by an altruistic standard. Because there is no potential pressure or coercion from a recipient or family member who is known to them, there is no direct relationship to the recipient, nor are there expectations of seeing firsthand the postoperative benefits to the recipient. On the other hand, altruism was not the only acceptable motive for the NDD that was considered by the conference participants. Several other ethically acceptable motives for the NDD could be identified such as religious beliefs, wishing to reciprocate to society, or wishing to honor an individual who died waiting for a transplant. Notwithstanding these considerations, the motives of an NDD warrant a thorough exploration to determine psychosocial suitability. Therefore, to provide some guidance in recommending acceptable motives and to accomplish the elements of informed consent as stipulated by the Live-donor Consensus Statement (1), categories of *unacceptable* donor expectations were defined. These reasons for donor exclusion are listed in Table 2.

Data regarding the long-term psychological consequences of being a directed donor disclose that most kidney donors' experience increased self-esteem after donation (10). A di-

# Table 2. Nondirected donor expectations and misperceptions

- An unrealistic expectation or demand by the donor that the transplant would be free from rejection and failure
- The misperception by the donor that if the transplant is not successful, it is because of a personal failure as a donor
- Monetary compensation for donation that would ignore current federal law prohibiting payment to the donor for a transplanted organ
- A desire for media attention (that could not be supported by the transplant center)
- A response or remedy for a psychological malady, such as severe depression, low self esteem, or other underlying mental illness
- A desired selection of the recipient by gender, race, or ethnicity
- A desired involvement in the recipient's life after donation, possibly unwanted by the recipient, that could not be supported by the transplant center.

rected donor is usually rewarded because a loved one or friend has enjoyed improved health and quality of life from the donation. Most donors are pleased that they donated, and would do so again. Because directed donors typically have a bond with the recipient, both donor and recipient may share a support network of family, friends, and acquaintances. This is inherently not the case for the NDD. No help from the recipient or from the recipient's family is an option because they are unknown to the recipient. In nondirected donation, the donor must have support separate from the recipient. This confirms the importance of considering how the NDD family or significant others of an NDD will respond to the donation (e.g., will they be available during and after hospitalization?).

The transplant center (or local OPO) can provide an additional service to the NDD by offering institutional support and encouraging participation in organ donation support groups, chat lines, and donor mentoring after donation. These opportunities for interaction can also help the NDD more realistically prepare for the donor experience. Such opportunities should be offered to NDD and directed donors alike. Finally, the transplant center is not obligated to participate in any process that does not conform to its medical and ethical standards. All transplant centers have a responsibility to uphold their practice standards and to refuse an organ donation from a person whose emotional and medical risks are unacceptable according to the center's experience and judgment.

#### Compensation for the Nondirected Donor

The direct payment of money as a motivation for nondirected donation violates Title III: Prohibition of Organ Purchase of the National Organ Transplant Act (NOTA) of 1984 (11). The transplant center has an obligation to advise the NDD (and the recipient) that a direct payment or any other form of compensation cannot be allowed for the nondirected donation. Equally important, the recipient should not be made vulnerable to any demand of the NDD either before or even years after the transplant. As is true for all live-organ donors, reimbursement for out-of-pocket expenses such as travel and lodging does not violate NOTA (1); however, participants acknowledged that there are limited available resources to assist with donor-related expenses. In terms of financial consequences, the NDD may be at risk of expending more personal resources than a directed donor because the NDD may not have access to the assistance that might be available for a familial recipient-donor (e.g., through fundraising or a fundraiser). Further, conference participants resolved to encourage government agencies, private corporations, and employers to permit paid leave for organ donation. For example, legislation has recently been enacted that enables a 30-day leave without loss of pay for all federal and some state employees who donate an organ (12). The U.S. military has long considered live-kidney donation to be a suitable reason for medical leave of active duty personnel.

#### The Prisoner as a Nondirected Donor

Conference participants cited instances of directed organ donation from prisoners that were accomplished with ethical propriety, psychosocial suitability, and informed consent. Prisoners' rights are usually not compromised when it comes to family relationships. Therefore, an imprisoned relative usually has an opportunity for directed donation, if found to be medically and psychologically suitable. However, the issue of a prisoner who wishes to be an NDD brings complexity to the donation process because prisoners have restricted freedoms. Nondirected donation should not be entertained if the prisoner's expectation is to either commute or reduce the duration of the sentence. The prisoner may expect that donation will provide some atonement for the guilt associated with a crime, or that donation would permit the prisoner to be viewed in a more positive light by family or society. Such reasons, for any type of donor, should be scrutinized cautiously as a reason for undergoing the risks associated with any surgery.

Logistical problems associated with prisoner donation include transporting the prisoner to the transplant center for evaluation, additional surveillance, the operative procedure, the hospital stay, and the follow-up care. The additional expenses for the service of the prison guards throughout the evaluation and hospitalization of the NDD prisoner may be prohibitive, and there is no current financial source to cover these costs for prisoner NDD. The conference participants acknowledged that all of these obstacles also apply to the directed donor who is a prisoner; however, the recipient knows the directed donor and may be more receptive to paying the additional costs associated with the prisoner's donation.

Another important caution in the use of a prisoner as an NDD is the heightened risk of infectious disease to the recipient. Even though the serological screening of the prisoner's blood sample may be negative, there could still be the risk of transmission of infectious disease if the blood sample is taken in a period of time in which serologic testing would not detect the prisoner's exposure to HIV or hepatitis. As with any NDD, prisoner donation could render the recipient vulnerable to unwanted infectious contacts or medical demands years after the transplant. Assuring confidentiality for both donor and recipient during the time of donation must be a priority. However, maintaining donor anonymity would be difficult, especially with the need to disclose the donor's prisoner status to the recipient before transplantation. The recipient would have to weigh such risks in his or her final decision to proceed. Thus, with all of these considerations, the conference participants recommended that prisoners not be considered for nondirected donation.

# The Live-Donor and Deceased-Donor List Exchange as a Type of Nondirected Donor Program

An NDD coming forward to donate to an unspecified recipient has been discussed above, akin to a blood or bone marrow donation in which the NDD gives to a stranger waiting on the list. Another type of unspecified donation to a stranger has been developed by a live-donor (LD) or deceased-donor (DD) list exchange. This approach arises when a directed donor is determined to be medically and psychosocially suitable but incompatible by ABO blood type or T-cell crossmatching with the intended recipient. By an LD or DD list exchange, the following takes place: the LD (in this instance also in effect an NDD) gives to a candidate of the same blood type who is waiting on the list and is unknown to the donor. In exchange, the first available deceased-donor kidney from the region's pool is then offered to the intended but incompatible recipient of the LD. The individuals in the LD or DD list-exchange program have a compelling reason to donate: to expedite a loved one's receipt of an organ. Therefore, they would not fulfill the criteria of an NDD by motivation and support systems. Although their donation is not to their loved one, their loved one receives a direct benefit from the donation, as with any other directed donor.

Nevertheless, by the definition of an NDD as one who donates to an unspecified recipient, the LD or DD list exchange makes the live donor an NDD in that process. Thus, this approach of live-organ donation was discussed at this conference. The LD or DD list exchange is being piloted with the approval of UNOS, by New England transplant centers (UNOS Region 1), and by the WRTC. The biological circumstance of the LD or DD list exchange usually develops when an A or B blood-type donor is unable to give to an O bloodtype recipient. The disadvantage of this approach is that the waiting time of an O blood-type candidate waiting for a deceased-donor kidney could be extended by the incompatible recipient of the LD receiving a priority for a kidney offer (1). Thus, the waiting time of patients on the list whose transplant is delayed by a priority afforded to the incompatible recipient must be carefully monitored. However, the opportunity to provide for two transplant recipients instead of one is the impetus to proceed with these pilot programs.

#### Selection of the Recipient

The use of the nationally endorsed UNOS formula for the distribution of deceased-donor kidneys as the basis for determining the NDD recipient was recommended by conference participants to provide selection objectivity, to avoid physician or program bias, and to maintain public confidence in the NDD program. However, the component of the UNOS system of cadaver kidney allocation that emphasizes degrees of HLA matching is not as consequential to the other considerations for identifying the NDD recipient as for identifying a live-organ donor recipient. Because it is now known that HLA matching is no longer a requirement for assuring the success of an unrelated live-donor transplant, it was suggested that the UNOS algorithm be modified to retain only the requirements for 0 mismatch, pediatric transplants, sensitization points, and waiting time.

The recipient of the NDD should be determined in advance of the transplant, using criteria that are clearly stated, consistently applied, and publicly disclosed. A suggestion that the NDD might be given an opportunity to express a preference or exercise an influence over selecting a recipient, in terms of class, race, or gender, was viewed as a potentially unethical exercise of discrimination. Some ethicists have proposed that the NDD be afforded an opportunity to participate in the selection of a recipient because the donation of the organ is properly considered a gift (13); however, many participants concluded that if the donor were to be given such a role in directing the gift, the organ could no longer sensibly be considered a "nondirected" donation. Furthermore, a consensus emerged identifying a clear hazard: allowing the NDD the option to express a selection preference could lead to inequities and discrimination beyond those inherent in directed donation. Substantially more candidates would then, in effect, "jump the line" ahead of others who, for arbitrary reasons of being in unfavored categories, would not be helped by such donation. From a surgical perspective, ideally the recipient should be in an operating room adjacent to the NDD to preserve the advantages of live-donor transplantation that enhance long-term success, including a short cold ischemia time and a low rate of delayed graft function.

# Communication Between the Nondirected Donor and the Recipient

The principle of anonymity (the current standard for cadaveric donation) also was recommended for the NDD. This well-established standard brings a responsibility to the OPO and the transplant center to maintain the anonymity of both the donor and recipient, unless both wish to meet or correspond sometime after the transplant. It is also possible that the NDD and the recipient may both wish to meet before the transplant procedure. However, permitting the NDD to meet or correspond with the intended recipient before transplantation might open the door for the donor to withdraw because of disapproval of the recipient, or expose the recipient to requests for some form of material assistance; thus, some transplant centers have prohibited such a meeting (6). These centers have additionally safeguarded anonymity by not having the donor and recipient hospitalized on the same floor, to avoid inadvertent contact of family members, although such logistics can, at times, prove difficult.

After transplantation, the donor and recipient may wish to meet or correspond in person, or by Internet or mail. A thorough discussion of the risks and benefits associated with such a meeting or communication should be provided to both parties (14). The hazard of a posttransplant meeting brings the possibility of disappointment by the donor or recipient becoming aware of each other. Some will choose not to proceed with a meeting because either the donor or the recipient may not wish to have a presence in the other's life. Nevertheless, no matter what caveats are offered in pretransplantation counseling, the transplant center and the OPO must underscore in the recipient's informed consent that life-long anonymity cannot be guaranteed, especially if the NDD solicits media attention as a misguided motive to donate. Similarly, the OPO must be cautious in educational brochures that show photos of the NDD and recipient together, implying that such a meeting is commonplace after the transplant.

#### Media Involvement

Educating the public about the opportunity of live-organ donation was distinguished from the solicitation for live-organ donors through media advertising, either by transplant centers or by desperate patients awaiting transplantation. The professional transplant community is well aware that transplant candidates have brought the plight of their illness to the attention of the media (including television, local newspaper, and even by church bulletins). It is not within the purview of either a transplant center or an OPO to prevent either the NDD or the recipient from seeking media attention—both donor and recipient should be informed of this possibility before the transplant. However, conference participants recommended that an NDD who seems overly interested in media coverage should not be accepted because of the potential impact of media coverage on the recipient's anonymity and privacy. Likewise, conference participants considered recipients who utilized the media to solicit and secure a live donor as bearing more careful examination, in the event of potential rewards in exchange for seeking an organ.

#### Nondirected Donor Follow-Up

The long-term psychological consequences to the NDD are not known. Further collection of data will be necessary by centers conducting NDD surgery so that appropriate information is available for future NDD guidelines and for prospective volunteers who wish to be considered as an NDD. A national data base should be developed that would record the medical and psychological outcomes from such donations so comparisons can be made with the existing directed-donor population while assuring the continued health and benefits of such volunteers. Particular attention to the donor's overall well being after donation is critical, if we continue to allow such individuals to give so generously of themselves. Educational materials that provide accurate and comprehensive information about risks to the donor are important to facilitate a reflective discussion between the NDD and family, friends, or medical professionals, and especially the personal physician. These materials should state the risk of complications and death associated with live-kidney donation.

The conference participants were aware of two directed kidney-donor deaths and one case of a directed donor who existed in a persistent vegetative state (PVS) for 18 months (at the time of the conference). Considering the outcome of the PVS donor and estimating that approximately 9000 live kidney donations were performed during this period, a rate of one donor death in 3000 occurred in this most recent period of time. A national survey of transplant centers (15) has been conducted to obtain precise data regarding the complications of kidney donation to assist the NDD in making a decision to donate or not. Until a national registry can be established, transplant centers involved with nondirected donation should maintain a registry of their own experience, detailing the medical and psychological follow-up of their patients.

### CONCLUSION

The success of live-donor kidney transplantation is a testimony to the goodness of those wanting to help family, loved ones, and others in need. The transplant community can now honor the goals of those who wish to donate a kidney to a stranger because of the need and the existing benefits derived from unrelated live donation. Although long-term data regarding the well-being of directed donors has been established, it is not yet clear what the psychological impact of donation will be on the NDD who may not have the reward of seeing the health of their recipients improve. Until such data are forthcoming, health care professionals should proceed with caution. When approached by NDD volunteers, centers should make certain that a thoroughly informed consent is accomplished that details risks, assures safety, and determines that the goals and expectations of the NDD and the recipient can be realized.

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#### APPENDIX

Participants of the National Conference on the Nondirected Live-Organ Donor

Patricia L. Adams, M.D., Wake Forest University School of Medicine; Stephen T. Bartlett, M.D., University of Maryland; Lori Brigham, Washington Regional Transplant Consortium; James Burdick, M.D., Johns Hopkins University; David J. Cohen, M.D., Columbia Presbyterian Medical Center; Gabriel M. Danovitch M.D., University of California Los Angeles Medical Center; John Davis, National Kidney Foundation; Francis L. Delmonico, M.D., Massachusetts General Hospital; Reverend Mark D. Edington, Harvard College; Richard N. Fine, M.D., SUNY HSC at Stony Brook; Robert S. Gaston, M.D., University of Alabama at Birmingham; Susan Gunderson, M.H.A., Life-Source; Douglas W. Hanto, M.D., Ph.D., University of Cincinnati College of Medicine; William Harmon, M.D., Children's Hospital, Boston; Cheryl L. Jacobs, M.S.W., L.I.C.S.W., FUMC-University of Minnesota; Alan Leichtman, M.D., University of Michigan; Marc I. Lorber, M.D., Yale University School of Medicine; Richard S. Luskin, New England Organ Bank; Arthur J. Matas, M.D., University of Minnesota; David McLean, Ph.D., United Resource Networks; Robert A. Metzger, M.D., Trans-Life; Linda Ohler, M.S.N., R.N., C.C.T.C., National Institutes of Health; Brian J. Pereira, M.D., New England Medical Center; Thomas G. Peters, M.D., Jacksonville Transplant Center at Shands, Jacksonville; Richard J. Rohrer, M.D., F.A.C.S., New England Medical Center; Lynn Rothberg-Wegman, M.P.A., Division of Transplantation, Health Resources and Services Administration; Velma Scantlebury, M.D., Presbyterian University Hospital; Laura A. Siminoff, Ph.D., Case Western Reserve University; J. Richard Thistlethwaite, M.D., Ph.D., University of Chicago; Robert M. Veatch, Ph.D., The Kennedy Institute of Ethics, Georgetown University; Pedro J. Vergne-Marini, M.D., Dallas Nephrology; and W. Ben Vernon, M.D., Centura Porter Adventist Hospital.

Organizations Participating in the National Conference on the Nondirected Live-Organ Donor

American Societies of Transplantation and Transplant Surgeons, The American Society of Nephrology, The United Resource Networks, The United Network for Organ Sharing, The Association of Organ Procurement Organizations, The National Institutes of Health, and The Division of Transplantation of the Health Resources and Services Administration.

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# **ERRATUM**

In the article by Ben-Ari Z, Hochhauser E, Burstein I, et al. Role of anti-tumor necrosis factor- $\alpha$  in ischemia/reperfustion injury in isolated rat liver in a blood-free environment. Transplantation 2002; 73(12):1875–1880, the footnote section should have noted that this work was supported by a grant from the Sackler School of Medicine, Tel-Aviv University, Tel-Aviv, Israel.

In the Transplantation May 15 supplement, Patient Management by Neoral  $C_2$  Monitoring: From Science to Practice, in the article by Nashan B, Cole E, Levy G, and Thervet E. Clinical validation studies of Neoral  $C_2$  monitoring: a review. 2002; 73(9 suppl): S8, data shown in Table 4 were transposed. The correct data are shown in the table below:

TABLE 4. Clinical status of de novo liver transplant recipients managed by Neoral C<sub>2</sub> or C<sub>0</sub> monitoring (17, 29)

Status at 12 months	$\substack{\text{C}_2 \text{ monitoring} \\ (n=158)}$	$C_0$ monitoring $(n=148)$	P value
Incidence of acute rejection (all patients)	26.6%	33.5%	NS
Incidence of acute rejection (HCV-negative patients)	21.2% (n=99)	33.0% (n=100)	P < 0.05
(3 months)			
Proportion of biopsy-proven rejection episodes	47%	70%	P = 0.02
graded moderate to severe (all patients)			
Mean cumulative steroid dose	4879 mg	5640 mg	NS
Patients continuing azathioprine	10%	27%	0.02
Mean serum creatinine*	$118~\mu mol/L$	$115~\mu\mathrm{mol/L}$	NS

HCV, Hepatis C Virus; NS, not significant.

<sup>\*</sup> Pollard S. AST/ASTS 2001, Abstract 1123.