

The living donor advocate: a team approach to educate, evaluate, and manage donors across the continuum

Living donor transplant has developed as a direct result of the critical shortage of deceased donors. Federal regulations require transplant programs to appoint an independent donor advocate to ensure safe evaluation and care of live donors. Ethical and pragmatic issues surround the donor advocate. These issues include the composition of a team versus an individual advocate, who appoints them, and the role that the advocate(s) play in the process. A team approach to donor advocacy is recommended. Common goals of the independent donor advocacy team should be protocol development, education, medical and psychosocial evaluation, advocacy, support, and documentation throughout the donation process. The team's involvement should not end with consent and donation but should continue through short- and long-term follow-up and management. Ultimately it is the goal of the independent donor advocacy team to assist donors to advocate for themselves. Once deemed medically and psychologically suitable, donors must determine for themselves what they wish to do and must be free to vocalize this to their team. The decision to donate or not affects the donor first. Optimal outcomes begin with prepared, educated, uncoerced, and motivated donors, and it is the team's goal to help donors reach this point. (*Progress in Transplantation*. 2009;19:64-70)

Dianne LaPointe Rudow, NP-BC, DNP, CCTC
New York Presbyterian Hospital,
Columbia University, New York, NY

Corresponding author: Dianne LaPointe Rudow, NP-BC, DNP CCTC, New York Presbyterian Hospital Center, 622 West 168 Street, PH 14, New York, NY 10032 (e-mail: dl349@columbia.edu)

To purchase electronic or print reprints, contact:
The InnoVision Group
101 Columbia, Aliso Viejo, CA 92656
Phone (800) 809-2273 (ext 532) or (949) 448-7370 (ext 532)
Fax (949) 362-2049
E-mail reprints@aacn.org

Since 2001, the transplant community has been in agreement that

The person who gives consent to be a live organ donor should be competent, willing to donate, free from coercion, medically and psychosocially suitable, fully informed of the risks and benefits as a donor, and fully informed of the risks, benefits, and alternative treatment available to the recipient.¹

How this goal should be reached in individual transplant programs has been the subject of much debate within and outside of the transplant team. Most support the use of a live donor advocate in the evaluation process. Ethical and pragmatic issues surround the donor advocate: who should be the advocate or who should make up the team of advocates, who appoints the advocate(s), and what role the advocate(s) play in the process. This article is focused on the issues surrounding advocating for live donors, describing the many advocates in the transplant process and how each advocate can be used for optimal outcomes.

Definition of Advocacy

Before a donor advocate can be selected, one must first understand what function the advocate should per-

form in the donation process. *Webster's dictionary*² defines an advocate as follows:

1. One that pleads the cause of another; specifically one that pleads the cause of another before a tribunal or judicial court.

2. One that defends or maintains a cause or proposal.

If this simple definition is the primary focus of a donor advocate, then this person would be limited to helping determine what the donor wants and convincing the transplant team to follow the donor's wishes. Some view the donor advocate as a "protector" whose focus is to protect the donor from harm. Others view a donor advocate as someone who advises the donor. Most would agree that the donor advocate's role is much more complex.

The Advisory Committee on Organ Transplantation has made recommendations to the Department of Health and Human Services regarding advocates. That committee recommends that an independent donor advocate represent and advise the donor so as to ensure that ethical principles are applied to the practice of all live donor transplantation.³ The committee recommends that each transplant center identify and provide an independent and trained patient advocate whose primary obligation is to help donors understand the process, the procedure, and the risks and benefits of live organ

Table 1 Summary of living donor regulations in the United States⁵⁻⁷

	Center for Medicare and Medicaid Services	Organ Procurement and Transplant Network/United Network for Organ Sharing	New York state
Medical evaluation	✓	✓	✓
Psychosocial evaluation	✓	✓	✓
Independent advocate	✓	✓	✓
ABO verification before removal	✓		
ABO verification before transplant	✓		
ABO checked twice	✓		
Multidisciplinary team	✓	✓	✓
Policy development, including	✓	✓	✓
Evaluation/donor selection			
Discharge plan			
Postoperative management			
Role of donor advocate			
Consent process			
Follow-up			
Documentation	✓		✓
Donor suitability in medical record			
Consent			
Disclosure			
Physician qualification	✓	✓	
Nursing care			
Education	✓		✓
Nurse-to-patient ratio			✓
Hospital support (ie, anesthesia, radiology)	✓		✓

donation; that advocate should protect and promote the interests and well-being of the donor.

The ethics committee of the Transplantation Society published an Ethics Statement of the Vancouver Forum on live lung, liver, pancreas, and intestine donors. That statement recommends inclusion of a health care professional in the donation process who is exclusively responsible for the donor's evaluation and welfare and is not concerned with the recipient.⁴ This advocate provides education in a repetitive fashion and ensures that policies and procedures are in place and followed to safeguard donors.

During routine follow-up more than 3 months after donation with the independent donor advocacy team (IDAT), random donors were asked what it is a live donor wants from an advocate. Replies of donors at New York Presbyterian Hospital varied (oral communications, April 2006):

1. "Look out for my best interest."
2. "Make sure I am healthy enough to donate."
3. "Just let me do this."
4. "Educate me about the risks, carefully evaluate me, and then tell me I am going to be OK."
5. "Don't treat me like a cadaver."
6. "Give me my own health care team."

Donors and clinicians recommend that a donor advocate's primary focus be the donor; the advocate should be involved in the process of evaluation, education, and

decision making regarding the ability to proceed with donation, while remaining separate from the recipient.

Regulatory Advocacy

Because of the controversy and variability in practices among live donor transplant programs around the country, regulatory bodies have been forced to advocate for live donors by mandating high-quality donor care at a regulatory level. Some may view this approach to advocacy as paternalistic. Live donor regulations are summarized in Table 1.

After the death of a living liver donor in 2002 in New York, that state was the first to respond with regulation of live donor practices. They formed a committee that made recommendations on quality improvement in living liver donation.⁵ The state of New York made the recommendations into regulations in February 2004. The regulations require that each transplant program have an IDAT to evaluate all donors. Additional regulations define aspects of informed consent, education, evaluation, perioperative care, staffing models, and follow-up recommendations. Kidney guidelines are under development.

In March 2007, the Centers for Medicare and Medicaid published new conditions of participation for transplant centers and made specific programmatic requirements for those centers performing live donor transplants.⁶ The regulations include the following:

- Development of criteria for selection of living donors that are consistent with general principles of medical ethics,
- Requirement for prospective living donors to receive medical and psychosocial evaluation,
- Development of policies for the informed consent process,
- Generation of written policies outlining the evaluation and management of live donors,
- Requirement for centers to document suitability of living donors in medical records,
- Development of processes to review blood type of the living donor before removal of the organ and of the recipient before implantation, and
- Requirement for all centers to supply a living donor advocate or team of advocates.

On September 18, 2007, the United Network for Organ Sharing (UNOS) amended its bylaws regarding the structure of live donor liver and kidney programs.⁷ They specify the personnel, resources, and protocols that are required to be approved as a live donor program. Programs must submit an application for approval to provide live donor services to the UNOS board of directors. Each center must document specific qualifications of the surgeons performing live donor operations, have appropriate coverage plans, an independent donor advocate, protocols regarding the medical evaluation, psychosocial evaluation, preoperative and postoperative management, follow-up, and informed consent. Additionally, a published resource document on informed consent of living donors⁸ is available for transplant professionals to develop informed consent processes that comply with the regulations. Resource documents for the medical evaluation of kidney and liver donors are being developed.

The goal of the regulations of live donor programs is to safeguard those volunteering to be live donors and standardize care. Interpretations of the regulations differ among transplant programs and surveyors, thereby resulting in ongoing variation in practice; however, at minimum, programs will have a donor advocate, qualified personnel, and protocols for evaluation, consent, and management of all potential live donors.

Transplant Program as Advocate

All transplant programs desiring approval to perform live donor transplants must provide resources, both personnel and financial, to be compliant with current regulations to safeguard donors. A live donor nurse coordinator designated to the program can be instrumental in understanding the regulations and developing and implementing written protocols to ensure that all potential and actual live donors receive the education and care they need. The nurse coordinator can oversee all aspects of care for the donor. Educational resources, both written and multimedia, should

be developed and used to supplement verbal education provided by members of the transplant program. Quality improvement initiatives can be used to monitor compliance and improve overall care of donors.

Controversies Surrounding Who Should Be the Donor Advocate

The most debated issue among centers has been about who the donor advocate should be and how “independent” the advocate should be. When considering who should be appointed as a donor advocate, the following possibilities have been considered: a donor-appointed advocate, a member of the transplant team not caring for the particular recipient, a hospital employee outside the transplant team such as a clergy member or a physician not involved with organ transplant, an organ procurement agency (OPO), and a team of advocates. Others have insisted that the donor advocate be a physician. All meet the requirements of federal and state regulations, but some may be better overall advocates for donors’ needs.

The donor advocate must have medical sophistication,⁵ so clergy may not be the best choice, and given the variations in religious beliefs, not all donors may identify with a clergy member. A donor-appointed advocate may lack the medical knowledge to truly advocate for the donor and may be too close to the donor to look at the situation objectively. A member of the OPO typically evaluates deceased donors and may lack the experience and knowledge of the risks to live donors to advocate appropriately for donors. All donors require medical evaluation by a physician, but this person may or may not be the “independent advocate.” A member of the transplant team is medically sophisticated about transplant, understands the implication, risk, and benefits of donation, and so long as he or she is not caring for the recipient, will have the objectivity to accurately advise a donor. However, a team of advocates may advocate for donors more completely.

A Team Approach to Advocacy

New York state’s Committee on Quality Improvement in Living Liver Donation requires that the donor advocate be a team of people (not an individual). The main functions of the advocate team are to protect the interest and well-being of the donor; structure the process of informed consent; discuss care with the transplant team; educate the donor about the medical, psychosocial and financial implications of donation; explain the evaluation process; determine donor suitability; discuss formal conclusions with the donor; and ensure continuity of care throughout the process.⁵ The benefit of this approach is that each member brings his or her own area of expertise and personal experiences to the team. A donor brings his or her own experiences and views to the group and has more than

one person to rely on or confide in. It is important for advocates to understand end-stage organ-specific disease and the transplant process so that they can depict the process accurately to the donor. Roles and responsibilities should be delineated ahead of time so that each member knows the boundaries from which to function.

Transplant centers that use the team approach include an internal medicine physician, a transplant coordinator/nurse practitioner, a medical social worker, and a psychiatrist. Some centers include the financial coordinator and an inpatient nursing supervisor to enhance the education process.⁹ An ethicist should be available for consultation. All members of the IDAT should be medically sophisticated in aspects of the organ-specific transplant process and be able to describe complications of donation as well as both local and national statistics on the outcomes for donors and recipients. The social worker and or psychiatrist should be skilled in individual and family counseling and must understand the entire donation and transplant process. The team must work together so that critical teaching is done and is documented by at least 1 member of the team. The team may also include other members such as a hepatologist, nephrologist, or surgeon.

Role of the IDAT

The IDAT carefully evaluates the potential donor and attempts to give the donor all the information required to make an informed choice. This information includes descriptions of the evaluation process, tests required, surgical procedure, risks, benefits, psychiatric effects, financial implications, long-term outcomes, and recipient issues such as chance of survival, disease process, and organ allocation.^{3,9} All donors are informed that if the IDAT team, in collaboration with the donor surgeon, believe the donor's risk is greater than what is currently medically acceptable, the IDAT team will turn down the donor regardless of what the donor would like to do. If there is discord on the donor team, the internist is deemed the mediator for medical concerns and the psychiatrist is the mediator for psychiatric concerns.¹⁰ If the group is unsure of how to proceed, the transplant ethicist is consulted. New York state gives the donor surgeon the ability to overrule the IDAT's decision so long as the reason is documented in the medical record.⁵ Regular participation of the donor surgeon in donor selection meetings is encouraged and may result in collaboration and less discord.

Common Goals of the IDAT

The common goals of the IDAT should be development of protocols for evaluation and management, education, regulatory compliance, medical and psychosocial evaluation, advocacy, support, short- and long-term follow-up, and documentation throughout the donation and transplantation process.

Before donation, the goal of the IDAT is to evaluate the donor medically and evaluate the donor's ability to make a decision, develop an individualized education plan in accordance with their education level, balance the hopes and expectations of the donor against the medical risks involved, and assess whether donation is voluntary.

The IDAT's role does not end with donation. The medical care of a donor after surgery, including inpatient and outpatient follow-up, is a critical need that should be met by the IDAT. Donors should be informed of the need for long-term follow-up, both because it ensures careful monitoring of complications but also because such follow-up is required by the Centers for Medicare and Medicaid and the Organ Procurement and Transplantation Network and UNOS. Postoperative psychological complications, previously underreported, have been identified and also should be addressed.¹¹ Psychological complications include anxiety, depression, and feelings of disappointment when expectations have not been met.

Additionally, the IDAT must support individuals who are turned down by the medical team as donors. If potential donors opt not to donate, the IDAT can help them talk with their family regarding their decision. Some recommend "making up a medical reason" so that the donor can save face with their family. It is not our policy to be deceitful but rather vague. The IDAT and the potential donor work together to decide what is said. If new medical conditions are diagnosed, referral for treatment is required.

The overall goal is to ensure that the act of donation is both an autonomous and educated decision and that the donor is medically cared for and psychologically supported throughout the continuum.

Structuring the Evaluation

In order to prepare donors better for the donation, the evaluation should be structured in such a way as to provide education throughout the process. Donor need to be given the educational tools to comprehend what they are being told and understand why they are undergoing the tests and procedures that are required. The Figure shows an optimal process for evaluation.

Initially a donor calls for evaluation and the live donor coordinator performs a telephone triage to rule out any obvious contraindications, assess ABO compatibility, and briefly describe the process and risks. Next, written educational material and consent to begin evaluation³ are sent to the potential donor and an evaluation is set up. Review of this material gives donors an overview so that they have some understanding of the process when they come to the evaluation. The first visit is with the live donor coordinator, who provides one-on-one education with the donor and his or her support system and takes a medical history. This

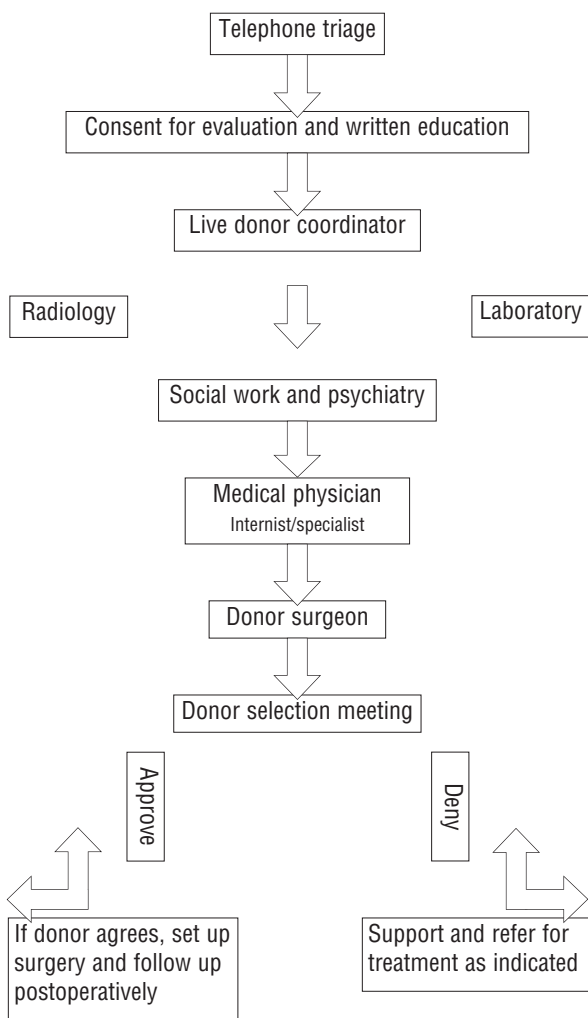


Figure Structuring the living donor evaluation. The donor may opt out at any point in the process.

one-on-one education in “lay terms” is the best way for donors to understand complicated medical terms and procedures so that when they meet with the surgeon to discuss operative risks they are better able to understand complicated medical jargon.

Next, the laboratory and medical tests are performed, beginning with least expensive and least invasive and continuing to the more expensive and invasive.¹² These tests will vary depending on the donor’s age and medical history, and the organ being donated, but the goal is to assess the health of the donor, predict risk, rule out infection and cancer, and determine transplantability of the organ to be donated.

The psychosocial evaluation is done by a social worker, psychologist, and or psychiatrist who assesses psychiatric history, mental competence, ability to cope, relationship with the intended recipient, social support, financial hardships, and education of the donor. It is recommended that family or friends of the donor attend part of these visits to assist in donor preparation.

Evaluations by medical physicians and surgeons should be performed once results from the laboratory and radiological tests are completed so that donors can be evaluated and educated about their risk in relation to their results. Once they have been educated and prepared by the live donor coordinator and psychosocial team and have been given time to absorb the information, they are better prepared for more medically sophisticated evaluation.¹³ Depending on the results, additional testing may be required.

After the evaluation is completed, the IDAT and the surgeon meet to discuss the donor’s evaluation to determine suitability. Deliberation occurs, and when consensus is reached the donor is approved or denied. The live donor coordinator transmits the results of the evaluation to the donor by phone and in writing so that the donor understands the outcome of the evaluation. If the IDAT and the donor are in agreement to proceed, the donation will occur.

The Informed Consent Process

The IDAT’s most critical role is during the consent process. Critical concepts related to informed consent for live donors that must be addressed are shown in Table 2. Informed consent has 3 components: information, comprehension, and voluntariness.¹⁴ Information must be conveyed about the evaluation, procedures, risks, benefits, and alternatives to living donation. Comprehension entails presenting the information in an organized systematic fashion using language and learning styles appropriate for the donor in question. Presenting the information in a rapid, disorganized fashion may limit comprehension of the full impact of donation on the donor. Some recommend a 2-week “cooling off” period to fully process the data.⁵ Voluntariness requires that consent be free from coercion or undue influence.

It is the role of the IDAT to explore the motivations for donation and help donors understand their motivation and the implications of donation. Greater emphasis on motivation occurs when the donor has no blood or emotional bond to the recipient.¹⁵ Coercion/pressure, both internal and external, exists in all circumstances and is difficult to measure and fully assess. One of the tasks of the IDAT is to assess carefully for pressures, often unknown to the potential donor, and determine whether it is appropriate to proceed. Situations such as a transplant candidate with hepatocellular carcinoma at risk for metastasis or a dialysis patient with limited vascular access put unavoidable pressure on many family members. The IDAT must educate and support the donor and raise all the appropriate issues for discussion so that the donor can make an appropriate decision about donation. It may, however, be impossible to determine secret financial incentives, but discovery of such incentives should lead to termination

Table 2 Components of informed consent

Assess for
Capacity to make medical decisions
Ability to communicate choice
Understanding of information provided
Appreciation of options available
Rational decision-making capability
Coercion
Inform about
Donor evaluation procedure
Surgical procedure
Recuperation period
Potential medical or psychosocial risks to donor
Short- and long-term follow-up care requirements
Potential psychiatric benefits
Quality of life after donation
The fact that communication between the donor and the transplant center will remain confidential
The availability of alternative treatments for the transplant recipient
The recipient's risks, recurrent disease, and chances for survival
National and center-specific outcomes for recipients and living donors as data are available
The possibility that the donor's medical evaluation could reveal conditions that the transplant program must report to governmental authorities, such as infection with the human immunodeficiency virus
The possibility that future health problems related to the donation may not be covered by the donor's insurance and the ability to obtain health disability or life insurance may be affected
The donor's right to opt out of donation at any time during the donation process
The fact, if applicable, that if the recipients transplant is not provided in a Medicare-approved transplant center, it could affect the transplant center's ability to have the patients immunosuppressive drugs paid for under Medicare Part B

of the donor evaluation. As long as the donor comprehends the risks involved and is free of coercion and financial gain, the donation is most likely appropriate.

The Family as Advocate

A critical advocate in the process is the donor's "family." The definition of family varies depending on the donor, but all donors need someone close to them to be available to assist them in the decision-making process as needed, advocate for them, and assist and support them in their care throughout the process. It is important for the family to attend the education sessions with donors to serve as an additional resource for information. Often donors do not recollect all that is said, and a second set of ears is useful to comprehend the magnitude of the process. The role of the family includes learning about donation to assist the donor in making the right decision (Table 3). The support team may not agree with the decision to donate, but must agree to assist in the care before and after donation. Roles include providing logistical, practical, financial, emotional support as well as advocacy before and after donation. Donors who do not have

Table 3 The family as donor advocate

Potential donors need to be willing to have family members educated about live donation
Family members must agree to be educated
Health care proxy is assigned and accepts responsibility
Concrete plan regarding finance, child care, transportation, care giving, and communication
Advocacy: willingness of family to create 2 teams of caregivers
Vigilant advocacy during inpatient stay: gatekeeper
Organized communication with the medical team
Accept discharge responsibilities for housing, nutrition, legal matters, and long-term follow-up.
May need to create a "family"
Communication of the division of labor

family in the traditional sense may need to create a "family." The IDAT team should assist the donor.

The Donor as Advocate

A diligent IDAT team is expected to educate and evaluate the donor to ensure optimal results, but team members work on the premise that potential donors are truthful about their medical history and their motivation to donate. Many potential donors have done research and have preconceived notions about donation. The IDAT must work with potential donors to correct any misconceptions they may have, explore their motivation and expectations, and give them the tools to advocate for themselves. Ultimately donors must advocate for themselves. If they do *not* want to donate, they must say so. If donors have a complication, it affects them the most. Frequently, a potential donor may need the assistance of one of the IDAT members to recognize his or her own hesitancy or reluctance to donate. Consequently the team must provide the donor with a safe environment in which to discuss declining to proceed with donation. A successful evaluation facilitates the process to give donors the tools they need to advocate their wishes.

Conclusion

Donor advocacy is present on multiple levels: regulatory (government), institutional, transplant program, and then the donor and his or her family. Each plays an important role in donor advocacy. It is evident that a team of advocates is best to service the needs of donors. The role of the advocate does not end with donation. It is crucial that the IDAT manage complications, monitor recovery, provide follow-up, and support the donor throughout the process.

Optimal outcomes begin with a sound program to care for donors and a prepared, educated, uncoerced, and motivated donor. It is the IDAT's job to help achieve

this and at the same time maintain stewardship to the donor, the donor's family, the recipient, the transplant program, persons on the transplant waiting list, and the field of transplantation.

References

1. Abecassis M, Adams M, Adams P, et al. Consensus statement on the live organ donor. *JAMA*. 2000;284:2919-2926.
2. Webster's Dictionary. <http://www.merriam-websters.com/Dictionary/Advocate>. Accessed July 9, 2008.
3. Consensus Report: Secretary Tommy G. Thompson's Advisory Committee on Organ Transplantation (ACOT). <http://www.organdonor.gov/research/acot.htm>. Accessed July 9, 2008.
4. Pruett T, Tibell A, Alabdulkareem A, et al. The ethics statement of the Vancouver Forum on the live lung, liver, pancreas and intestine donor. *Transplantation*. 2006;81(10):1386-1387.
5. New York State Committee on Quality Improvement in Living Liver Donation. A report to New York State Transplant Council and New York State Department of Health. <http://www.health.state.ny.us>. Accessed July 9, 2008.
6. CMS COP42 CFR Part 405, 482, 488, and 498. *Federal Register*. 2007;72(61). <http://www.cms.hhs.gov/CFCsAndCoPs/downloads/trancenterreg2007.pdf>. Accessed July 7, 2008.
7. Transplant Programs. <http://www.unos.org/policiesandbylaws>

8. Consent for Living Donation. http://www.unos.org/Content-Documents/Informed_Consent_Living_Donors.pdf. Accessed July 9, 2008.
9. Rudow DL, Brown RS Jr. Evaluation of living liver donors. *Prog Transplant*. 2003;13(2):110-116.
10. Rudow DL, Brown RS Jr. The role of the independent donor advocacy team in ethical decision-making. *Prog Transplant*. 2005;15(3):298-302.
11. Trotter JF, Hill-Callahan M, Gillespie BW, et al. A2ALL Study group. Severe psychiatric problems in right hepatic lobe donors for living donor liver transplantation. *Transplantation*. 2007;11:1506-1508.
12. Trotter JF. Selection of donors for living donor liver transplantation. *Liver Transplant*. 2003;9(10, suppl 2):S2-S7.
13. Charlton M, Ventura K. Education and the transplant patient. In: LaPointe Rudow D, Ohler L, Shafer T, eds. *A Clinician's Guide to Donation and Transplantation*. Lenexa, KS: Applied Measurement Professionals Inc; 2006.
14. Bulger RE, Heitman E, Reiser SJ. *The Ethical Dimensions of the Biological and Health Sciences*. New York, NY: Cambridge University Press; 2002.
15. Dew M, Jacobs C, Jowsey S, et al. Guidelines for the psychosocial evaluation of living unrelated donors in the United States. *Am J Transplant*. 2007;7:1047-1054.