Evaluation of the Living Kidney Donor – a Consensus Document from the AST/ASTS/NATCO/UNOS Joint Societies Work Group

On June 16, 2006, the Health Resources and Services Administration (HRSA) published a notice in the Federal Register in which the Secretary of Health and Human Services directed the Organ Procurement and Transplant Network (OPTN) to develop policies regarding living organ donors and organ donor recipients. The notice stipulated that noncompliance with such policies will subject OPTN members to the same consequences as noncompliance with OPTN policies regarding deceased donor transplantation. In response, the Board of Directors of the OPTN adopted changes to the Bylaws requiring transplant programs that perform living donor transplants to develop and follow written protocols that address all phases of the living donation process, including the evaluation, pre-operative, operative, and post-operative care, as well as the submission of data (Federal Register volume 71).

To assist the Living Donor Committee of the United Network for Organ Sharing (UNOS) in developing policy and bylaws that govern Living Donor Kidney Transplant Programs, a Joint Societies Steering Committee composed of representatives of the American Society of Transplantation (AST); the American Society of Transplant Surgeons (ASTS); the Organization for Transplant Professionals (NATCO); and UNOS was established by HRSA and the OPTN contractor on April 9, 2010 in Rockville, MD (attachment). This Steering Committee met to discuss and develop a new process for incorporating clinical input into developing OPTN/UNOS policies with the potential to direct or prescribe medical care.

The need for such a process had been identified during the course of OPTN/UNOS attempts to develop policies that are more specific and detailed regarding OPTN/UNOS member requirements in the area of living donor protections. During the discussion, it was noted that early involvement of the societies in the OPTN/UNOS policy development process, for the purpose of identifying the appropriate medical requirements and the appropriate level of specificity of such requirements, would be an important advance.

Therefore, the Steering Committee formed a Joint Societies Work Group (JSWG) consisting of appointed members of the represented Societies on June 30, 2010. These individuals were:

1. AST: Robert S. Gaston, MD; Didier A. Mandelbrot, MD; Robert W. Steiner, MD
2. ASTS: Stuart M. Flechner, MD; Joe Leventhal, MD; Lloyd Ratner, MD
3. NATCO: Catherine Garvey RN CCTC; Patricia McDonough RN CCTC
4. OPTN/UNOS: Matthew Cooper, MD; Christie Thomas, MD; Cynthia Forland, PhD

The charge to the JSWG was to *"…provide recommendations to OPTN/UNOS regarding appropriate requirements for the medical evaluation (including psycho-social evaluation) and informed consent of potential living kidney donors as well as post-donation follow-up and data submission."*

In order to accomplish the charge of the JWSG three documents were created, which represent the consensus reached by all members of the JSWG. These include (1) a Guidance document for Informed Consent of Living Kidney Donors; (2) a position paper on

the Medical and Psychosocial Evaluation of the Living Kidney Donor; and (3) recommendations for Donor Follow-up and Data Submission.

The JSWG believes that living kidney donor transplantation is an essential part of kidney transplant practice, and that this activity can only go forward if potential donors have full faith and confidence that their transplant professionals and transplant centers are looking out for their best interests and well being. To provide this degree of confidence the JSWG believes these guidelines represent the best available information for transplant centers to help potential donors make the decision to donate in an informed fashion, and to maximize donor safety. Although live donor transplantation in the United States commenced in the 1960's, it is understood that precise accurate information on long-term donor follow-up beyond 30-40 years is not known. The formal acquisition of detailed long-term follow-up information on donor outcomes may require extramural organization and financial support, and should not be considered an essential component of transplant center compliance.

Live donor kidney transplantation will always be a balance between utility for the recipient and safety for the donor. Therefore, the JSWG consensus has recommended that transplant centers use caution when considering borderline characteristics for young donors. In addition, The JSWG appreciates that there may be alternative choices to reach similar conclusions, and has attempted to point out these alternatives when appropriate. Lastly, the JSWG believes these Guidelines represent a living document for which changes

may be necessary over time as new information on living kidney donation becomes available.

I. INFORMED CONSENT OF LIVING KIDNEY DONORS

Purpose

The Joint Societies Working Group developed this consensus document to assist transplant professionals in developing consent processes for all living kidney donors.

Introduction

Education is important to enable the potential donor to understand all aspects of the donation process, especially the concept of risk and benefit.

The potential donor should understand:

1) That he or she will undertake risk but will receive no medical benefit from the operative procedure of donor nephrectomy.

2) That there are both general risks of the operation as well as center-specific risks.

This consensus document is separate from any additional informed consent requirements for potential donors participating in the OPTN Kidney Paired Donation Program.

Living Donor Consent

The consent process for any potential living donor should include, but is not limited to, the following:

a. The assurance that the potential donor is willing to donate, free from inducement and coercion, and understands that he or she may decline to donate at any time. Donors will be offered an opt-out opportunity that is protected and confidential, with provision of sufficient time for the potential donor to reflect on his or her decision before and after

evaluation. The independent donor advocate (IDA) must be available to provide support during this process.

b. The provision of teaching materials (e.g., written or video) that explain all phases of the living donation process. If printed, materials should be written at an appropriate reading level and provided in the potential donor's native language if possible. Materials should be available for review outside of the transplant center when necessary, independent interpreters should be provided to make certain the potential donor comprehends all phases of living donation and its associated risks and benefits. To be meaningful, risks and benefits should be presented semi-quantitatively, using the center's best data-based estimates (e.g. 30% donor's kidney function lost with donation; about 50% kidney transplant survival at 15 years).

c. Assurance that the transplant center will take all reasonable precautions to provide confidentiality for the donor and recipient, as appropriate.

d. Disclosure that it is a federal crime subject to $50,000 fine or five years in prison for any person to knowingly acquire, obtain or otherwise transfer any human organ for valuable consideration. In certain cases, donors may be reimbursed for limited travel expenses and may receive subsistence assistance.

e. Disclosure that living donor transplant programs must provide an Independent Donor Advocate (IDA). The IDA must know the facts of donor education about risk and benefit so donor inattention and misunderstanding can be detected. The donor must demonstrate an understanding of the risks and benefits of donation to the IDA. IDA responsibilities include, but are not limited to the following:

- Promote the best interests of the potential living donor
- Advocate for the rights of the potential donor
- Assist the potential donor in obtaining and understanding information regarding the:

  1) Consent process;

  2) Evaluation process;

3) Surgical procedure;

4) Medical and psychosocial risks;

5) Benefit and need for follow-up.

f. The stipulation that transplant centers will provide potential donors with both national and center-specific outcomes from the most recent SRTR center-specific report. This information should include, but not be limited to the center's 1-year patient and graft survival, national 1-year patient and graft survival, and notification about all CMS outcome requirements not being met by the transplant center.

g. The provision of education that discusses how much kidney function will remain after the donor nephrectomy and what the potential impact on the donor might be in light of the established epidemiology of chronic kidney disease (CKD) and end-stage renal disease (ESRD).

1) Donors lose 25-40% of kidney function at donation

2) Baseline risk of ESRD is the same as those in the general population with the same risk profile

3) Should they develop CKD, their progression to ESRD may be more rapid than people with two kidneys. They may also be at a higher risk for CKD if they sustain damage to the remaining kidney.

4) Current practice is to prioritize prior living donors who become transplant candidates.

h. Disclosure of alternate procedures or courses of treatment for the recipient including deceased donor transplantation.

- The donor should be made aware that a deceased donor kidney might become available for the recipient before the living donation is consummated.

- Potential donors should be provided a realistic estimate of the likelihood of successful transplantation for the recipient. If there are factors that increase the risk of morbidity or mortality in the

recipient these must be discussed openly with the donor, but only if the potential recipient has agreed to share this information.

i. The disclosure that the donor will receive a thorough medical and psychosocial evaluation.

In order to be adequately informed, potential donors need to understand there are some risks associated with evaluation for live donation (including, but not limited to allergic reactions to contrast, discovery of reportable infections, discovery of serious medical conditions, discovery of adverse genetic findings unknown to the donor, discovery of certain abnormalities that will require more testing at the donor's expense or create the need for unexpected decisions on the part of the transplant team). The potential donor will need to consent to evaluation, which includes, but is not limited to the following:

- The donor must understand that the medical evaluation will be conducted by a physician and/or surgeon experienced in living donation to assess risks to the potential donor post donation. This will include a screen for any evidence of occult renal and infectious disease and medical co-morbidities, which may cause renal disease. In addition, the psychosocial evaluation will be conducted by a psychiatrist, psychologist, and/or social worker with experience in transplantation to determine decision-making capacity, screen for any pre-existing psychiatric illness, and evaluate any potential coercion.

- The donor must be informed that the center has the duty to justify reasonable medical and psychosocial risk, and that donors may be refused because of persisting uncertainty in these areas as well as for specific negative findings. Decisions of the transplant program are final and cannot be grieved. However, donors may be referred to another transplant program that may have different selection criteria.

j. A specification of the surgical and longer-term medical, psychosocial, and financial risks associated with being a living donor. These risks may be transient or permanent and include, but are not limited to the following:

i) Surgical Risks:

- Scars; Pain; Fatigue, etc;

- Decreased kidney function in kidney donors. Every kidney donor will experience a decrease in the kidney function compared to pre-donation. The amount will depend upon the potential donor's age and history. The anticipated change in individual kidney function is to be discussed with each donor.

ii) Potential Longer-Term Medical Risks:

- Abdominal or bowel symptoms such as bloating and nausea;

- Impact of obesity, hypertension or other donor-specific medical condition on morbidity and mortality of the potential donor; and,

- Findings in the donor medical examination -- and all donor risks -- must be interpreted in light of the known epidemiology of both CKD, which largely arises in mid-life, (40-50 years old) and ESRD, which usually occurs after age 60. The limits of a normal examination in a young donor to reduce lifetime risk must be acknowledged.

- Kidney failure and the need for dialysis or kidney transplant for the donor.

iii) Potential Psychosocial Risks:

- Problems with body image;

- Post-surgery depression, anxiety, emotional distress or PTSD (post traumatic stress disorder), the risks of which increase if the living donor and/or transplant recipient experience unexpected medical outcomes or problems; and,

- Impact of donation on the donor's lifestyle.

iv) Potential Financial Impacts:

- Personal expenses of travel, housing, child care costs and lost wages related to donation might not be

reimbursed; however, the potential donor should be informed that resources might be available to defray some donation-related costs;

- Need for life-long medical follow-up at the donor's expense; and,

- Impact of having the transplant in a hospital not approved by CMS to perform transplants may affect the recipient's ability to have the anti- rejection medications covered under Medicare Part B.

v) Potential Longer-Term Financial Risks:

- Loss of employment or income;

- Impact on the ability to obtain future employment including, but not limited to military service, law enforcement, aviation, and fire department employment;

- Impact on the ability to obtain or afford health, disability, and life insurance; and,

- Future health problems experienced by living donors following donation may not be covered by the recipient's insurance.

- Disclosure that transplant centers are required to report living donor follow-up information for two years. The agreement of the potential donor to commit to post-operative follow-up testing coordinated by the designated- transplant center a minimum of two years.

vi) Disclosure initially, and as a part of the final step in donor acceptance or refusal, that selection policies and protocols may vary significantly among reputable centers, specifically in accepting, or declining donors who may be at increased medical risk.