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.

III. LIVING KIDNEY DONOR FOLLOW-UP

The future of individuals who donate organs for transplantation is, by nature, unpredictable. Despite comprehensive and exhaustive living donor evaluative protocols, prognosticating the long-term outcome for an individual donor is difficult. Conclusions surrounding the safety of living organ donation are primarily based upon single-center homogeneous patient populations or incomplete non-validated large data sets. While 2-year follow-up of living donors should not be expected to yield definitive data regarding the long-term safety of organ donation, the provision of limited data at defined time points provides value. For example, finding abnormal kidney function at one of these time points would be relatively rare but of great importance to both the donor and the transplant community.

An individual's presentation to a transplant center with an interest in living donation should be recognized as the initial stages of a contract between two parties. The patient enters with the promise of an altruistic, selfless, and potentially life-saving gift of an organ for transplantation. The center promotes the safety of living donation and a genuine interest in the health of that individual beyond the date of donation. The parties together express an implicit trust in one another. As with all contracts, however imperfect, efforts must be made to ensure not only the expectations of both parties but also the spirit of the intentions that brought the two together. Mandatory follow-up at 6 months, 1 year and 2 years following surgery is the transplant community's responsibility to maintaining the public's trust and demonstrating a sincere interest in that contract we share with current and future living donors. With statements of its need at the initial encounter with a potential donor and a concentrated effort at bringing the parties together at these 3 time points, the donor is more likely to appreciate the significance of ongoing contact with the health care system beyond year 2 and continue regular, yearly, preventive health care visits and to become their own health care advocate. Regular contact with the centers also allows the donor programs to become familiar with issues that develop after donation providing an opportunity to proactively modify education or procedures to manage these situations.

Data collection at these time points must be pertinent, attainable, and related to the donation process, and not overly burdensome on the donor or the transplant center that provides such reports. These elements include:

1. Alive/Dead (Cause if known)
2. Hospital readmissions for donor related complications (wound, SBO, etc.)
3. Need for dialysis (Yes/No)
4. Development of post-donation diagnoses: hypertension, diabetes, cancer, other
5. Loss of income or livelihood due to donation

6. Loss of medical (health, life) insurance due to donation
7. Lab work - serum creatinine and urine protein in kidney donors

Although requests for more data or increased length of follow-up are desirable, the listings above should be an expected minimum on all donors following surgery at 6 months, 1 year, and 2 years. Transplant centers must demonstrate a documented effort of obtaining such data as an obligation to operate as a living donor transplant center. The working group acknowledges that these recommendations involve a very dynamic area and are likely to evolve over time as new information becomes available