

## **OPTN/UNOS PATIENT AFFAIRS COMMITTEE INTERIM REPORT**

October 13, 2011

The following is a summary of the PAC deliberations that occurred via Live Meeting on October 13, 2011.

The Committee met to review the *USPHS Proposed Guidelines for Reducing Transmission of HIV, HBV and HCV Through Solid Organ Transplantation*.

- The Committee received a brief overview of disease transmission statistics since the OPTN began tracking transmissions in 2006. This presentation was designed to help the Committee grasp the incidence of confirmed disease transmissions within the OPTN.
- The Committee also received a brief overview of the process for approaching potential donor families for consent to donate. In preparation for this presentation, the committee had received a written overview of the role of the OPO in organ procurement. The Committee also received a copy of a medical-social assessment used by a member OPO. The focus of the discussion was the OPO stance that every donor is a high risk donor until available evidence indicates otherwise.
- The Committee agreed that their first priority was to maintain the public trust in the OPTN. The Committee strongly supported the CDC emphasis on informed consent. At the same time, the Committee recognized the struggles inherent in attempting to define acceptable risk in a manner that can be easily understood by the general public.

The Committee further raised concerns regarding variability in standards for assessing risk while assessing deceased donors versus living donors. The Committee strongly felt that the proposed guidelines will compel living donor programs to become more aggressive in assessing behavioral history. Concerns were raised that this might serve as a disincentive for altruistic donors in particular.

The Committee voiced concern that citing all persons having 2 or more sexual partners in the previous 12 months has the potential to negatively impact the donor pool while not significantly impacting transplant safety.

The largest concern for the Committee was the issue of informed consent. The Committee strongly supports the need for education and discussion regarding high risk donors prior to the time of transplant. The Committee further recommended that high risk donor education be included in the periodic re-evaluation of persons on the waiting list.

The Committee also strongly encourages the development of standardized language for informed consent. This language should also include relevant real-world examples of risk e.g. your risk of a disease transmission from the organ are roughly the same as your risk of being hit by a bus on your walk to the car. These types of examples insure that the candidate has a practical understanding of what they have consented too. Standardized language further helps to support surgeons who have concerns regarding accepting organs from potential high risk donors by increasing their confidence in their patients ability to grasp the full extent of what they are consenting too.

The Committee agreed to have the liaison compose a summary of the discussion and provide it for their review by 10/20/2011. After final review, the statement would be submitted for inclusion in the full response from the OPTN.

- The Committee will meet via conference call on Thursday November 3, 2011 to continue review of Public Comment Proposals.