



American Society of Transplant Surgeons

July 8, 2010

Charles Alexander, RN, MSN, MBA, CPTC
President
Organ Procurement and Transplantation Network (OPTN)
United Network for Organ Sharing (UNOS)
700 North 4th Street
Richmond, VA 23219

Dear Mr. Alexander,

The Council and Executive Committee of the American Society of Transplant Surgeons (ASTS) on behalf of its constituency have reviewed and considered the following ten proposals that have been distributed by OPTN/UNOS in March for public comment through July 16, 2010. Below are the stated positions of the ASTS on these proposals.

Proposal 1: Proposed Ohio Alternative Local Unit (ALU)

The ASTS is **supportive** of this proposal as it is consistent with the OPTN Final Rule for broader sharing and forming sharing agreements between existing OPO's.

Proposal 2: Proposed One Legacy Split Liver Alternative Allocation System (AAS)

The ASTS **supports this proposal pending clarification**. The ASTS is supportive of a protocol agreed upon by all liver centers in the DSA that serves as an incentive to split appropriate livers using the other segment in a patient at the particular center where the first segment was used. ASTS requests that the proposal be **clarified that the left lateral segment or the left lobe is to be used in the most appropriate patient at that institution or affiliated pediatric institution as opposed to the current language that calls for use strictly in pediatric patients.**

Proposal 3: Region 2 Split Liver AAS

ASTS **supports** this proposal agreed upon by Region 2 transplant centers to incentivize transplant centers to split appropriate livers which will increase access to adult left lateral segment. By using the right lobe as the index case, the left lateral segment can be allocated to the most appropriate patient at the same institution or affiliated pediatric institution.

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Proposal 4: Proposal to Develop an Efficient, Uniform National Pancreas Allocation System

ASTS is **supportive** of a uniform pancreas transplant allocation system with a single pancreas/ SPK list that would include all diabetics on insulin with c-peptide < 2 OR c-peptide >2 and BMI<30.

Proposal 5: Proposal to Modify OPO and Transplant Center Requirements for Screening, Communicating and Reporting All Potential or Confirmed Donor-Related Disease and Malignancy Transmission Events.

ASTS **opposes** this proposal as written. While there are important features within this proposal, ASTS believes this proposal is too long and should be rewritten to include changes in nomenclature, clarification of current language and elimination of certain requirements that would allow for a reproducible process.

In Policy Section 2.2.2.1, ASTS suggests a change in nomenclature of “high risk” to “increased risk of disease transmission” instead of the proposed “increased risk for blood borne pathogens.”

In Policy Section 4.1, ASTS believes that the wording “additional testing and therapy” impacts informed consent. ASTS maintains that informed consent is best managed by the individual transplant center and is concerned that this proposal may result in organ wastage by negatively impacting the informed consent process.

Policy Section 4.4 mandates a Patient Safety Contact at each OPO to be responsible for managing information regarding a potential disease transmission or safety event. ASTS believes this position is unnecessary as this information should be reported to the program director who bears responsibility for managing the transplant procedure including potential disease transmission.

Proposal 6: Proposal to Update HLA Equivalences Tables

ASTS **supports** this proposal to update the HLA tables for acceptable and unacceptable antigens.

Proposal 7: Proposal to Require that Deceased Donor HLA Typing be Performed by DNA Methods and Identify Additional Antigens for Kidney, Kidney-Pancreas, Pancreas and Pancreas Islet Offers.

ASTS is **supportive** of this proposal that requires OPOs and their associated laboratories perform HLA typing of deceased donors by DNA methods which allows for the identification of HLA-A, -B, -Cw, -DR, -DQ antigens prior to making any organ offers.

Proposal 8: Proposal for the Placement of Non-Directed Living Donor Kidneys

ASTS is **supportive** of this proposal, **contingent upon adding clarification wording as described below**, that allows transplant centers that conduct the donor work-up to select the

recipient of non-directed living donor kidney based on a match run generated by the OPTN computer system.

The language as written does not exclude paired donation from the policy though it is stated in the preamble that it is excluded. The language should be re-written to specifically exclude exchanges from the policy. ASTS suggests the following clarification language which also includes a slight amendment to the title.

12.5.6 Placement of Non-directed Living Donor **Kidneys**

Prior to determining the placement of a non-directed living donor kidney, the transplant center must acquire a match run of its waitlist candidates. The transplant center may obtain the match run from its local OPO or the Organ Center of the OPTN Contractor. The transplant center must document the criteria used to place the non-directed living donor kidney. If the transplant center deviates from the sequence defined by the match run, the transplant center must document its rationale for not following the match run in addition to documenting the criteria used to select the kidney recipient. This documentation must be maintained and made available to the OPTN contractor upon request. **This policy does not apply to non-directed living kidney donors who consent to participate in a Kidney Paired Donation arrangement.**

Proposal 9: Proposal to Require Reporting of Non-Utilized and Redirected Living Donor Organs.

ASTS is **supportive** of this proposal that required transplant centers to report all instances where living donor organs are recovered but not used for transplant and living donor organs that are recovered but then redirected and transplanted into a recipient other than the intended recipient.

Proposal 10: Proposal to Require the Use of a Standardized Internal Label that is Distributed by the OPTN and that Transplant Centers Notify the Recovering OPO When They Repackage an Organ.

The ASTS **supports** this proposal.

Thank you for the opportunity to address these proposals. ASTS would be pleased to participate in any further definition or revision of one or all of these potential policies.

Yours sincerely,



Michael M. Abecassis, MD, MBA
President