MEMORANDUM

To: Dr. John Roberts, UNOS President
Mr. Brian Shepard, UNOS Interim CEO

From: Ms. Susan J. Nelson, Executive Vice President
American Society of Transplantation (AST)

RE: AST Comments on OPTN Policy Proposals

Date: June 14, 2013

On behalf of the American Society of Transplantation Board of Directors, I am attaching the Society's comments on the following OPTN policy proposals:

- Proposal to Redefine the Role of the Vice-President of the Board of Directors
- Proposal to Add Serum Sodium to the MELD Score
- Proposed Changes to the OPTN Bylaws Governing Histocompatibility Labs
- Proposed Update to the HLA Equivalency Tables in Appendix 3A
- Proposal to Clarify Requirements for Independent Donor Advocates (IDA) at Living Kidney Donor Recovery Centers
- Proposal to Change Pediatric Heart Allocation Policy

Please let me know if the AST can be of further assistance and thank you for the opportunity to comment on these policy proposals.

Cc: AST Board of Directors
Dr. Maryl Johnson, AST's UNOS Board Representative

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Proposal to Add Serum Sodium to the MELD Score

Summary of Proposal

The Committee is proposing to add serum sodium to the MELD score equation. Based on simulation modeling results, this change could reduce waiting list mortality by 50-60 deaths per year without adversely affecting post-transplant survival or negatively impacting any group of candidates (e.g., age, gender, ethnicity, diagnosis) ERRATA notice accompanies this proposal correcting information therein.

AST Comments:

While the AST is in favor of continuing to allocate organs based on the principle of "sickest first", we do wish to raise some concerns regarding this proposal, specifically:

1) There is the potential to "game" the system and intentionally lower the serum sodium;

2) There may be a significant increase in administrative burden for the coordinators in calculating the patients' MELD score, with a very small benefit in terms of the number of lives saved; and,

3) Most importantly, a significant amount of reprogramming and education would be required for a very small overall impact.

The AST respectfully submits that work should be concentrating on increasing the organ donor pool, decreasing discard rates and carefully examining the current HCC exception policies which are outdated.

Proposed Changes to the OPTN Bylaws Governing Histocompatibility Labs

Proposal Summary

This proposal represents the first phase of a comprehensive review of the OPTN Bylaws governing histocompatibility laboratories being conducted by the Histocompatibility Committee. This proposal contains several proposed changes, including an expanded definition of an OPTN histocompatibility laboratory, new required elements for agreements between histocompatibility laboratories and transplant programs or OPOs, a requirement that histocompatibility laboratories maintain the standards of the American Society for Histocompatibility and Immunogenetics (ASHI) or the requirements listed in the College of American Pathologists (CAP) checklists as of a date certain, a requirement that histocompatibility laboratories submit a Laboratory Coverage Plan to the OPTN Contractor, additional requirements for documentation when notifying the OPTN Contractor of changes in key personnel, and a separate, elevated performance standard for HLA typing performed for graded proficiency testing. Please note that the Committees comprehensive review of the Bylaws is ongoing and will continue throughout the upcoming year. This is the first of two proposals to be released as a result of the review.

AST Comments:

The AST supports this policy proposal.

Proposed Update to the HLA Equivalency Tables in Appendix 3A

Proposal Summary

The Committee is recommending several changes to the HLA equivalency tables, the majority of which are intended to reflect the OPTN policy requiring molecular HLA typing for deceased kidney, pancreas, and kidney-pancreas donors. Current OPTN Policy 3.5.14 requires the Histocompatibility Committee to update, on an annual basis, the HLA equivalency tables found in Appendix 3A of OPTN policies. The proposed changes to the tables referencing Matching Antigen Equivalences are intended to eliminate certain equivalences to better define a zero-HLA mismatch and an HLA-DR mismatch level for kidney, pancreas, and kidney-pancreas candidates in deceased donor allocation. The proposed changes in the tables referencing Unacceptable Antigen Equivalences eliminate certain equivalences for unacceptable antigens that are unnecessarily disadvantaging candidates in the screening process. In addition, the Committee is proposing changes to the section entitled Additional Unacceptable Antigen Equivalences to be used in Calculated PRA Only. These changes are intended to reverse previously approved policy changes that, if implemented, would have negative and unintended consequences for sensitized patients. Finally, the Committee is proposing a new, more user friendly format for displaying the tables in OPTN policy.

AST Comments:

The AST supports this policy proposal.

Proposal to Clarify Requirements for Independent Donor Advocates (IDA) at Living Kidney Donor Recovery Centers

Proposal Summary

This proposal would clarify existing requirements for independent donor advocates at living kidney donor programs, and would require living kidney donor programs to develop and follow new hospital-specific protocols addressing the qualifications, training and responsibilities of their independent donor advocates.

AST Comments:

The AST agrees with the intent of the policy, which is to address a need for greater clarity for transplant programs as to what is expected for the IDA, to ensure a more uniform experience that is not as dependent upon the transplant center and to make the expectations more explicit and consistent with CMS. However, we are not sure this has been achieved with this policy revision. Indeed, the proposed revision has actually created further questions.

Many believe that originally the purpose of the IDA was to prevent donors from being pressured by themselves, the center, or relatives, etc. That is why there were no formal criteria for the IDA. The IDA's duties now appear to be expanded so that they almost duplicate the activities of the rest of the center team. It takes a good deal of expertise to do all this well. The AST's specific comments are as follows:

Policy Proposal:

12.4. Independent Donor Advocate (IDA)

12.4.2 IDA Responsibilities
The IDA must

1. Function independently from the transplant candidate's team

Comment: Does this mean not being part of the transplant team meetings or dialogues of any sort, or just being neutral toward the possibility of donation? Does it mean not helping to arrange donor testing or not performing the functions that center social workers provide? Some programs divorce IDAs so much that they cannot be expected to have the knowledge needed to fulfill many of their responsibilities, especially in this new iteration, where they are dealing with almost every aspect of the donor selection process.

2. Advocate for the potential living donor and the living donor.

Comment: Greater clarity should be provided that "potential living donor" refers to the pre-transplant period and "living donor" refers to the post-transplant period. This infers that the IDA has responsibilities for the donor post donation. If so, how far out do the responsibilities extend and what are the post donation responsibilities? Is it that they must be available if needed? How does this differ from the live donor team's role post donation? The live donor committee needs to provide clarity and also not have the IDA duplicate the roles of the donor team in post donation follow up.

3. Demonstrate knowledge of living organ donation, transplantation, medical ethics, informed consent, and the potential impact of family or other external pressures on the potential living donor's decision about whether to donate.

Comment: This suggests that the IDA must possess the professionally competent knowledge of other team members. It would be ideal if UNOS could provide guidance or even educational materials to help define what constitutes "knowledge of living organ donation, transplantation, medical ethics, informed consent, and the potential impact of family or other eternal pressures on the potential living donor's decision about whether to donate". This is a very broad mandate depending on what knowledge is considered adequate. Completion of some educational or self assessment tool offered or endorsed by UNOS (perhaps something on line) would help standardize qualifications and aid programs in developing institutional policies and demonstrating compliance. The policy should clarify if the IDA should come from a medical background (i.e. Social worker, RN etc…) or if it is acceptable for the IDA to be a lay person. Will there be a standardized assessment of their knowledge? How will site surveyors determine if the IDA has the appropriate knowledge? Will specific points of knowledge about living donation and the informed consent process be assessed? If so these need to be enumerated.

12.4.3 IDA Protocols
The living kidney donor recovery hospital must develop, and once developed must comply with, written protocols for:

1. The composition of the IDA team, if the hospital uses a team

Comment: Does each member of the team have to have all the qualifications of a single IDA or just some of them? How do they decide and communicate? A team sounds unwieldy. Is one person in charge of the team? Also see comments under number 3 above.

3. The duties and responsibilities of the IDA, which must include at least the functions and duties listed throughout Policy 12.4

Comments: It is not clear how the IDA's training/expertise is quantified. Later, in the section on protocols, the regs state that the center must come up with their own qualifications and training for the IDA. This seems to perpetuate the problem that is trying to be corrected – that there is variability in the expertise and functioning of IDA's across transplant centers. We know UNOS is careful about not being too rigid with their guidelines, but the expressed purpose of this update is to "tighten up" the IDAs across centers. Allowing centers to define the qualifications of the IDA may result in significant variability from center to center.

4. The process the living donor recovery hospital will provide for the IDA to file a grievance when necessary to protect the rights or best interests of the living donor.

Comment: The AST suggests that there should first be an appeals process for adjudicating disagreements before filing grievances. The wording sounds adversarial. Teams with good working relationships often can deliberate, assess, and discuss and come to a conclusion before an issue ever needs to go to a grievance. Further, most IDA's work for the transplant center and as such it may be difficult for an IDA grievance to be heard objectively. Should the proposal be more specific i.e., all IDA grievances will be heard by an independent ethics committee?

5. The process the living donor recovery hospital will use to address any grievance raised by the IDA concerning the rights or best interests of the living donor.

Comment: There should be a process for participating in QAPI with the team as a whole to improve donor selection and care.

Proposal to Change Pediatric Heart Allocation Policy

Proposal Summary

The primary goal of this proposal is to improve waiting list mortality for pediatric heart candidates by modifying the pediatric heart allocation policy. To do so, this proposal includes four recommendations: 1) redefine Status 1A and Status 1B criteria; 2) increase the qualifying isohemagglutinin titer to 1:16 or less for candidates who are one year of age or older but registered before their second birthday and willing to accept ABO-incompatible heart offers; 3) change the allocation priority of urgent potential transplant recipients younger than one year of age and potential transplant recipients eligible to receive ABO-incompatible heart offers; and 4) eliminate the option to register heart candidates as in utero. Redefining pediatric heart Status 1A and Status 1B criteria will decrease waiting list mortality as the proposed changes yield an allocation system that is more dependent on a candidate's medical urgency, rather than the candidate's waiting time. Expanding the criteria to qualify for an ABO-incompatible heart transplant and increasing the prioritization of these candidates should also improve the waiting list mortality rate by safely increasing their access to donor hearts, and potentially increasing the number of transplants. Lastly, eliminating in utero registrations will save time and resources needed to allocate and procure donor hearts for pediatric candidates.

AST Comments:

The AST **overwhelmingly** supports the proposed changes. However, some specific questions/comments are provided as outlined below.

Pediatric Heart Status 1A

b) **Requires assistance with a mechanical circulatory support device**

- Will there be a modification for the 1A after VAD placement to drop to 1B after 30 days for older patients with devices that might be suitable for long term use? The 1A status for them may not be entirely justified or necessary.
- That transplant status goes up with placement of a VAD may increase the use of mechanical circulatory support tremendously. Patients may have devices placed sooner in the disease process. Will this be a bad thing or good?

d) Has ductal dependent pulmonary or systemic circulation…

- There is good justification in the literature, and in the data presented by the Committee, to support the new Status 1A (a), (b), (c), and (e) criteria. Maintaining criteria 1A (d), even in its revised form, is less well supported. Figure 12 demonstrates that patients meeting criteria (d) have a death rate of 37 per 100 patient years, well below patients meeting criteria (a) or (b) and intermediate between congenital heart disease patients and dilated cardiomyopathy patients listed under criteria (e). The AST would advocate for making criteria (d) ("Has ductal dependent pulmonary or systemic circulation with ductal patency maintained by stent or prostaglandin infusion;") a Status 1B criteria, and not a 1A criteria. Consideration could then be given to adding the following 1A criteria: "Has ductal dependent pulmonary or systemic circulation with ductal patency maintained by stent or prostaglandin infusion **AND requires infusion of an inotropic drug**." This change would result in an additional reduction in patients listed 1A of somewhere between 0 and 10%.

e) Has a congenital heart disease diagnosis, is admitted to the listing center hospital, and requires infusion of high dose or multiple inotropes. This criterion excludes minor congenital defects such as….

- Perhaps in addition to the word "minor", "repaired" or "corrected" defects should also be specifically excluded.

- The requirement that the admission must be to the listing center hospital to maintain 1A (e) status should be reconsidered. There are many qualified hospitals that can care for children with end stage heart failure and congenital heart disease. For many reasons, including quality of life and proximity to home, patients may be hospitalized on high dose inotropes at a non-listing center. In addition, this criterion provides confusion for patients who listed at multiple centers. For example, if a patient is listed as a Status 2 at Hospital A and Hospital B but subsequently admitted to Hospital B and placed on high dose inotropes, the child could be upgraded to Status 1A (e) by Hospital B. When Hospital B informs Hospital A of the admission and need for inotropes, the patient would be upgraded only to status 1B at Hospital A. Since the patient is equally sick whether admitted to Hospital A or B, the listing status should remain the same at both hospitals (i.e. be upgraded to 1A status at both centers).

ABO-incompatible registrations

The committee should be commended for proposing a change to the allocation algorithms for candidates eligible to receive blood group incompatible heart transplants. The Committee's concern with expanding ABO incompatible candidacy for older patients is also understood. That being said, there is case report data to suggest that older patients can receive ABO incompatible transplants with reasonable results. In addition, the ability to innovate is necessary to move the field of Pediatric Heart Transplantation forward. The Committee should consider developing a process whereby patients older than 2 years could be listed for an ABO incompatible heart transplant. This would allow the Wait List program to be revised with the ability to allow patients over 2 years old to be listed for ABO incompatible transplants in the future.

A potential process is the following. Patients > 2 years old, or between 1 and 2 years old with isohemagglutinin titers > 1:16, whom a center would like to list for potential ABO incompatible heart transplant would be presented to a National Pediatric Heart Review Committee. Important clinical variables, including blood type, weight range, isohemagglutinin titers, listing status, and current clinical status would be presented in a standard format. A brief clinical justification for the request would be written by the requesting center. The request would then be discussed and voted on by the review committee. If granted, patients would be listed for ABO incompatible heart transplant using the same process used for patients between 1 and 2 years of age where incompatible transplants would be seen as secondary matches. Centers would be required to obtain consent from patients and/or families acknowledging that ABO incompatible heart transplant in patients above 2 years of age or in patients age 1 to 2 with isohemagglutinin titers >1:16 is an innovative therapy and not standard of care.

All data on these requests, listings, and transplants would be collected to allow for outcomes assessment. Modifications to WaitList, DonorNet, and TEIDi which are necessary to allow such exceptions could be made contemporaneously with the other proposed changes in order to save time and effort. The National Review Committee would publish periodic updates on the progress of such listings and set guidelines for what would be considered reasonable and likely to be approved (i.e. patients less than 5 year s of age with isohemagglutinin titers less than 1:32).

Proposal to Redefine the Role of the Vice-President of the Board of Directors

Proposal Summary

This proposal would separate the roles of the Vice-President of the Board of Directors and the Chair of the Membership and Professional Standards Committee (MPSC). The bylaws currently require the Vice-President to serve as the Chair of the MPSC. As the responsibilities of the MPSC Chair have increased over time, it can be challenging for the Vice-President to get sufficient exposure to the broader governance issues that he or she will encounter as President. Separating the roles will allow for the Vice-President to spend that year involved in Board governance and preparing for his or her Presidential year, and will allow the MPSC Chair to serve a more traditional two-year term, providing more stability in that Committees leadership.

AST Comments

The AST supports this proposal to allow for better preparation of the Vice-President of the UNOS/OPTN Board of Directors in the governance of the organization. This change will also allow the Vice-President to have greater exposure to the work of the other UNOS/OPTN committees during this year of preparation. In addition, having a MPSC Committee Chair appointed for a two year term will provide more consistency and stability to that critical organizational committee. The AST would recommend that the individual appointed as Chair of the MPSC be required to have served on the MPSC for at least two years prior to appointment as Chair.